United States District Court,
N.D. California.

BRITESMILE, INC.; Britesmile Development, Inc,
Plaintiffs.
v.
DISCUS DENTAL, INC.; Salim Nathoo; and Oral Health Clinical Services, LLC,
Defendants.
and Related Counterclaim,
and Related Counterclaims.

No. C 02-3220 JSW

May 13, 2005.

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CLAIMS CONSTRUCTION ORDER

JEFFREY S. WHITE**, District Judge.**

This Court has been presented with a technology tutorial and briefing leading up to a hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). This Order construes the five claim terms selected by the parties, which appear in the patents at issue in this case, United States Patent Nos. 6,343,933 ("the "3 Patent") entitled "Light Activated Tooth Whitening Composition and Method of Using Same," and 6,536,628 ("the '628 Patent"), and 6,514,542 ("the '543 Patent") each entitled "Tooth Bleaching Compositions."

BACKGROUND

Plaintiffs Britesmile, Inc. and Britesmile Development, Inc. (collectively "Britesmile"), and defendant Discus Dental, Inc. are competitors in the field of tooth whitening products and services. On July 8, 2002, Britesmile filed this suit alleging infringement of the three patentsin-suit by defendant Discus, in addition to various other claims against defendants Discus, Salim Nathoo, and Oral Health Clinical Services, LLC. Britesmile subsequently amended the complaint several times; at present, the operative complaint is the

Third Amended Complaint filed on July 20, 2004. Discus answered the third amended complaint on August 3, 2004, and asserted counterclaims of patent invalidity, unenforceability, and noninfringement.

There are three patents at issue in this case. The first, the "3 Patent, claims a method for tooth whitening using light energy to activate photosensitive agents applied to the tooth surface. The '543 and '628 Patents relate to a method for bleaching or whitening teeth utilizing multi-ingredient tooth whitening compositions that are combined through the use of a static mixer immediately prior to application onto the tooth surface.

ANALYSIS

A. Legal Standard

The interpretation of the scope and meaning of disputed terms in patent claims is a question of law and exclusively within the province of the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In most cases, the court's analysis will focus on three sources: the claims, the specification, and the prosecution history. Markman v. Westview Instruments, Inc. ., 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

The starting point of the analysis is an examination of the specific claim language. "[T]he analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201-02 (Fed.Cir.2002) (internal quotations and citations omitted). Indeed, in the absence of an express intent to impart a novel meaning to a term, an inventor's chosen language is given its ordinary meaning. York Prods., Inc. v. Cent. Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996); *see also* Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed.Cir.2003) ("Claim language generally carries the ordinary meaning of the words in their normal usage in the field of invention."). The terms used within a claim bear "a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." *Id.* at 1202; *see also* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998) (recognizing that "the claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim"). The court's final construction, therefore, must accord with the words chosen by the patentee to mete out the boundaries of claimed invention.

The court may also look to intrinsic evidence, including the written description, the drawings, and the prosecution history, if included in the record, to provide context and clarification regarding the intended meaning of the claim terms. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324-25 (Fed.Cir.2002). The specification "may act as a sort of dictionary, which explains the invention and may define the terms used in the claims." Markman, 52 F.3d at 979-80. The specification can also indicate whether the patentee intended to limit the scope of a claim, despite the use of seemingly broad claim language. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed.Cir.2001) (recognizing that when the specification "makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question").

Intent to limit the claims can be demonstrated in a number of ways. For example, if the patentee "acted as his own lexicographer," and clearly and precisely set forth a definition of the disputed term in either the

specification or the prosecution history, the court will defer to that definition. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). In addition, the court will adopt an alternative meaning of a term "if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." Id. at 1367. Likewise, the specification may be used to resolve ambiguity "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." Teleflex, 299 F.3d at 1325.

However, limitations from the specification (such as from the preferred embodiment) may not be read into the claims, absent the inventor's express intention to the contrary. Id. at 1326; *see also* CCS Fitness, 288 F.3d at 1366 ("[A] patentee need not describe in the specification every conceivable and possible future embodiment of his invention."). To protect against this result, the court should refrain from consulting the intrinsic evidence until after reviewing the claims in light of the ordinary meaning of the words themselves. To act otherwise, "invites a violation of [the controlling] precedent counseling against importing limitations into the claims." Texas Digital, 308 F.3d at 1204-05.

Dictionaries also may play a significant role in the determination of the ordinary and customary meaning of a claim term. The Federal Circuit has characterized dictionaries as "the most meaningful sources of information to aid judges in better understanding both the technology and the terminology used by those skilled in the art to describe the technology." Id. at 1203. "Such dictionaries include dictionaries of the English language, which in most cases will provide the proper definitions and usages, and technical dictionaries, encyclopedias and treatises, which may be used for established specialized meanings in particular fields of art." Inverness Med. Switzerland GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1369 (Fed.Cir.2002).

If the analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language, the court may then turn to extrinsic evidence, such as expert declarations and testimony from the inventors. Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed.Cir.2003) ("When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained."). When considering extrinsic evidence, the court should take care not to use it to vary or contradict the claim terms. Rather, it is more appropriately relied upon to assist in determining the meaning or scope of technical terms in the claims. Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996).

B. Claim Construction

The "3 Patent

1. "the tooth whitening composition comprises a transparent carrier compound, a transparent oxidizing compound, a photosensitizer precursor"

The phrase "the tooth whitening composition comprises a transparent carrier compound, a transparent oxidizing compound, a photosensitizer precursor" appears in three claims of the "3 Patent (claims 1, 11, and 26). FN1 Claim 1 of the ' 933 Patent reads (with the disputed phrase in bold):

FN1. Claim 1 contains an exact recitation of the phrase as stated above; Claims 11 and 26 sets forth the

components of the tooth whitening composition in a slightly different order: "the tooth whitening composition comprises a transparent oxidizing compound, a transparent carrier compound, and a photosensitizer precursor".

1. A method for light-activated tooth whitening comprising the steps of:

applying a tooth-whitening composition to one or more teeth, wherein **the tooth whitening composition comprises a transparent carrier compound, a transparent oxidizing compound, a photosensitizer precursor** which when in contact with the surface of a stained tooth becomes a photosensitizing agent, wherein the photosensitizing agent when exposed to actinic light activates the oxidizing compound to facilitate tooth whitening at the surface of the teeth, and

exposing the tooth-whitening composition to actinic light to activate the oxidizing compound.

Britesmile proposes the phrase be construed as "the tooth whitening composition comprises a carrier compound, an oxidizing compound, and a photosensitizer precursor, which when in contact with the surface of a stained tooth becomes a photosensitizing agent where the entire tooth whitening composition is capable of transmitting greater than 70% light energy at a specified wavelength or within a wavelength range when measured through a 1-2 mm layer of the composition." Discus offers the construction, "in the context of a particular composition, the carrier compound and the oxidizing compound are each 'transparent' i.e. each has a greater than 70% transmission of light at a specified wavelength or within a specified wavelength range when measured through a 1mm thick gel containing the component. It does not require that the entire composition be 'transparent'." This Order does not adopt either proposed construction.

The crux of the parties' dispute is whether the claim requires that the entire tooth whitening composition be transparent or only those named components, namely the carrier compound and the oxidizing compound. A peripheral issue in dispute relates to the thickness of the composition. Britesmile asserts that the claim, when read and construed as a whole, requires that the composition allow light to reach the tooth surface, and therefore, the plain meaning of the claim dictates that the entire composition must be transparent. Discus counters that Britesmile's proposed construction rewrites the claim language and impermissibly imports a limitation from the specification into the claim. The parties agree that the patent expressly defines the term transparent to mean "having greater than 70% transmission of light at a specified wavelength or within a wavelength range." ("3 Patent at col. 6:58-60.)

Looking first at the specific claim language, the claim instructs that the tooth whitening composition comprises a carrier compound, a oxidizing compound, and a photosensitizer precursor. FN2 The word "transparent" expressly modifies "carrier compound" and "oxidizing compound." Discus asserts that the claim is otherwise silent regarding whether the remaining components, *i.e.,* the photosensitizer precursor, must be transparent. Moreover, Discus argues that the existence of the open-ended phrase "comprises" in the claim language indicates that the tooth whitening composition may have ingredients-transparent or not-in addition to those specifically listed in the claim. *See, e.g.,* Genetech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed.Cir.1997) (" 'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.").

FN2. The parties agree that a "photosensitizer precursor" is "an ingredient of a composition that, in the

context of the particular composition and application, will, when in contact with the surface of a stained tooth, become a photosensitizing agent, wherein the photosensitizing agent when exposed to actinic light activates an oxidizing compound in the composition." (Second Revised Joint Claims Construction Statement Following Markman Hearing at 1.)

Reading the claim as a whole, as the Federal Circuit instructs the court to do, the remaining claim language qualifies the disputed phrase. The claim states that following the application of the tooth whitening composition, "the photosensitizing agent when exposed to actinic light activates the oxidizing compound to facilitate tooth whitening at the surface of the teeth." Thus, the claim teaches that a photosensitizing agent is formed when the photosensitizer precursor comes into contact with the surface of the tooth. When the photosensitizing agent on the tooth's surface is exposed to actinic light, it activates the oxidizing compound. This process thus facilitates the whitening process. Accordingly, pursuant to the plain meaning of the claim language, the actinic light must pass through the tooth whitening composition and must reach the surface of the tooth.

The intrinsic evidence supports this construction. The Federal Circuit has repeatedly warned that there is sometimes a fine line between reading a claim in light of the specification and reading a limitation into the claim from the specification. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed.Cir.1998). Nevertheless, where the specification as a whole makes clear "that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims" accordingly. Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1370 (Fed.Cir.2003), *cert. denied,* 541 U.S. 1063, 124 S.Ct. 2390, 158 L.Ed.2d 963 (2004).

A review of the patent reveals that the invention was directed, in part, at "provid[ing] tooth whitening compositions that are relatively transparent to light energy in the wavelength range at which tooth chromogens absorb in order to allow exposure of the tooth enamel surface to said light energy while in contact with said tooth whitening compositions." ("3 Patent at col. 5:14-20.) The description of the summary of the invention begins: "The present invention encompasses methods for whitening teeth, wherein a stained tooth surface is contacted with (i) a tooth whitening composition that is transparent to photoactive light and (ii) a photosensitive agent that is responsive to wavelengths of light that are transmitted through the whitening composition and, after contacting with the composition and agent, the tooth is exposed to a biologically safe and effective level of photoactinic light in order to enhance the ability of the oxidizing compound in the whitening composition to effect rapid tooth whitening." (Id. at col. 5:29-38.) Finally, the abstract describes the invention as "a tooth whitening composition having a transparent first component that is a carrier compound and a transparent second component that is an oxidizing compound which when applied to a stained tooth and exposed to actinic light is activated to facilitate tooth whitening." (Abstract.)

The description of the preferred embodiments discussing the use of an oxidizing compound that includes a photosensitizer precursor (as opposed to the separate application of a photosensitizing agent and the oxidizing compound) all expressly disclose that the compound should be transparent to actinic radiation in order to allow the wavelength specified light energy to reach the tooth surface. For example, the preferred embodiments teach that "a photosensitizer precursor may be included directly within the oxidizing composition, where it does not readily absorb light in the visible region of the spectrum from 400 to 700nm." (Id. at col 8:27-37.) A further description teaches that "the invention includes contacting the tooth enamel surface with an oxidizing compound which contains a photosensitizer precursor, whereby said precursor is seen to absorb actinic radiation in the range of 350 to 700nm only after contact with said tooth

surface." (Id. at col. 10:13-17.) Consistent with these descriptions, the preferred embodiment examples discuss the use of transparent compositions. (*See* id. at col. 14:64-66, col. 16:41-43, col. 17:21-25 & table 4.)

In addition, the specification distinguishes the invention from the prior art compositions "that include a light (or heat) absorbing additive dispersed directly in and homogeneously throughout the oxidizing compound" and "which are ... opaque to most wavelengths," by "allowing actinic radiation to penetrate through the oxidizing compound, which is placed directly onto the tooth surface to be whitened." (Id. at col. 6:26-42 ("The inventive compositions ... allow actinic radiation to reach the stained tooth surface at higher power densities than prior art compositions that are specifically designed to absorb light.").) Thus, the specification teaches that the invention, as a whole (and not merely as a preferred embodiment), requires that the composition be sufficiently transparent to allow actinic light at a specified wavelength to reach the tooth surface.

Because an analysis of the intrinsic evidence resolves any ambiguities in the disputed phrase, the Court declines to rely on the extrinsic evidence submitted by the parties. *See* Vitronics, 90 F.3d at 1583.

The parties additionally proffer language regarding the required thickness of the tooth whitening composition to be applied. The claim language is silent on this issue. The parties refer the Court to the preferred embodiment examples, which describe tests performed by the inventor using a 1-2 mm layer of gel. For the precise reasons stated above, the Court declines to read these limitations, absent the inventor's express intention to the contrary, into the claim language. Here, the invention as a whole does not clearly contemplate that the use of a specified thickness of the tooth whitening composition. Merely because the examples given in the preferred embodiments used a particular thickness of gel does not "suggest that the very character of the invention requires the limitation to be a part of every embodiment." Alloc, 342 F.3d at 1370; *see also* Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed.Cir.1996) (admonishing that "[i]t is usually incorrect to read numerical precision into a claim from which it is absent").

The Court construes the phrase "the tooth whitening composition comprises a transparent carrier compound, a transparent oxidizing compound, a photosensitizer precursor" as: **the tooth whitening composition comprises a transparent carrier compound, a transparent oxidizing compound, a photosensitizer precursor which when in contact with the surface of a stained tooth becomes a photosensitizing agent, with the entire composition having greater than 70% transmission of light at a specified wavelength or within a wavelength range.**

The '543 and '628 Patents

The parties agree that for all intents and purposes relevant to claim construction, both the '543 and'628 Patents share the same specification. The parties dispute three terms found in these patents: (1) "the second formulation is substantially free of the hydrogen peroxide"; (2) "substantially free of an alkaline pH adjusting agent"; and (3) "alkaline pH adjusting agent," contained within the larger second term. These terms appear in claims in both the '543 (claim 2 and 18) and '628 (claim 2) Patents. The claims read as follows (with the disputed phrase in bold):

'543 Patent:

2. A method for whitening the teeth of a subject comprising: providing a multi chamber vessel, the vessel

including a first chamber having a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation **is substantially free of an alkaline pH adjusting agent;** and

a second chamber having a second formulation comprising an alkaline pH-adjusting agent and wherein **the second formulation is substantially free of hydrogen peroxide;**

the first formulation or the second formulation including a thickener and

applying pressure to the multi chamber vessel so as to force the first and second formulations through a mixer to form a mixture which then emerges from a single exit, the mixture being thickened, aqueous hydrogen peroxide containing composition having a pH of greater than 5.5; and

contacting the mixture to the teeth of the subject for less than one hour.

18. A method for whitening the teeth of a subject comprising:

providing a kit including a first tube and a second tube, the tubes adapted to keep apart two formulations, the first tube and the tube respectively include:

a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation is **substantially free of an alkaline pH adjusting agent;** and

a second formulation comprising an alkaline pH-adjusting agent and wherein **the second formulation is substantially free of hydrogen peroxide;**

the first formulation or the second formulation including a thickener and mixing the first formulation and the second formulation to form a thickened, aqueous, hydrogen peroxide containing mixture, wherein the mixture has a pH of greater than 5.5; and

contacting the mixture to the teeth of the subject for less than one hour.

'628 Patent:

2. A single exit multi compartment vessel with a mixer, whose compartments are adapted to keep apart two formulations and whose compartments respectively include:

a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation **is substantially free of an alkaline pH adjusting agent;** and

a second formulation comprising an alkaline pH-adjusting agent and wherein **the second formulation is substantially free of the hydrogen peroxide;**

the first formulation or the second formulation including a thickener and whereby applying pressure to the vessel forces material from the compartments through the mixer to form a thickened, aqueous hydrogen peroxide containing mixture emerging from the single exit in the vessel, wherein the mixture has a pH of greater than 5.5.

2. "the second formulation is substantially free of the hydrogen peroxide"

Britesmile proposes the definition "the second formulation has no more than an insubstantial amount of hydrogen peroxide." Discus proposes "no more than a trace amount of the hydrogen peroxide is present in the second formulation. Trace amounts could be introduced, e.g., by the manufacturing process."

The parties originally agreed to the meaning of this phrase. During briefing in preparation for the *Markman* hearing, Britesmile acknowledged that the agreed upon construction "violates well-settled Federal Circuit Law" and proposed instead that the term be construed consistently with its plain and ordinary meaning. Following the hearing, the parties submitted a Second Revised Joint Claims Construction Statement and requested that the Court intervene and define the term. The parties both assert that the Court should apply the plain and ordinary meaning of the claim language.

The Court construes the phrase to mean: **the second formulation contains no more than a trace amount of hydrogen peroxide.**

3. "alkaline pH adjusting agent"

Britesmile proffers that the term "alkaline pH adjusting agent" means: "an agent which functions to raise the pH of the formulation ." Discus proposes instead "an agent that, when added to water, has a pH above 7." The crux of the parties dispute turns on whether the agent actually functions to adjust the alkaline pH or whether it is merely capable of so functioning.

Discus asserts that the proper construction of the term, viewed in light of the invention as a whole, must take into account that an alkaline pH adjusting agent may be present in a solution, notwithstanding the fact that it cannot actually raise the pH of that solution. In support of its argument, Discus directs the Court's attention to claim 1 of the '543 and '628 Patents. FN3 In this claim, the first formulation contains, among other components, an anhydrous carrier-a carrier that contains no water. The claim further specifies that the first formulation is substantially free of an alkaline pH adjusting agent. Discus asserts that because a formulation comprised of an anhydrous carrier does not have a pH, then the alkaline pH adjusting agent may be present, but not "functioning" until the first formulation is combined with water. Britesmile responds that claim 1 merely requires the *carrier* to be anhydrous and not the entire formulation. Britesmile additionally points out that the first formulation "comprises" among other things the anhydrous carrier, and thus other components, including water, could be present in the formulation.

FN3. Neither claim is asserted in this litigation. Nevertheless, "the words of the claims themselves, both asserted and unasserted, ... define the scope of the patented invention." Vitronics, 90 F.3d at 1582.

The specification does not provide an express definition of the term, rather, it merely sets forth examples of suitable pH adjusting agents. ('543 Patent at col. 3:49-52; '628 Patent at col. 3:52-55.) The Court agrees that there is a conceptual distinction between an agent that is actually raising the pH of a solution and one that is capable of having that impact under the appropriate conditions. Accordingly, Britesmile's proposed construction fails to account for the situation where the pH adjusting agent is added to a solution that is incapable of having a pH. Looking to the plain meaning of the claim language, one skilled in the art would understand the term to mean an agent that is capable of adjusting the pH of a solution toward the alkaline end of the scale, or in other words, an agent that is capable of raising the pH of a solution.

The Court construes the term "alkaline pH adjusting agent" to mean: **an agent that is capable of raising the pH level of the formulation.**

4. "substantially free of an alkaline pH adjusting agent"

Britesmile proposes the construction "lacks a sufficient amount of an agent that functions to raise the pH of the formulation enough to markedly decrease the stability of the hydrogen peroxide." Discus proposes the construction "no more than a trace amount of alkaline pH adjusting agent is present in the first formulation and, in addition, the amount of alkaline pH adjusting agent, if any, cannot markedly decrease the stability of the oxidizing agent. Trace amounts could be introduced, e.g., by the manufacturing process." The Court does not adopt either construction.

Discus' proposed construction fails to acknowledge the construction it proposed for "alkaline pH adjusting agent" discussed above. Having construed the term "alkaline pH adjusting agent" to mean "an agent that is capable of raising the pH of the formulation," the remaining issue is the proper construction of "substantially free."

The Court has previously construed "substantially free" in the context of the term "the second formulation is substantially free of the hydrogen peroxide." As discussed above, the parties indicated that the plain and ordinary meaning of the term was appropriate. In this context, however, the parties request the Court to read into the plain meaning the effect that the pH adjusting agent would have on the stability of the hydrogen peroxide. This construction is not supported by the claim language.

When engaging in claims construction, the court is bound by the presumption that "the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims." Fin Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed.Cir.2001). Nothing in the specification or file history suggests that "substantially free" should have a different meaning when used in the context of the alkaline adjusting agent.

There is no need to go beyond the plain and ordinary meaning here. The Court construes the term "substantially free of an alkaline pH adjusting agent" to mean: **contains no more than a trace amount of an agent that is capable of raising the pH level of the formulation.**

5. "pH of approximately 8.0"

Finally, the parties dispute the meaning of the term "pH of approximately 8.0." This term is found in claims in both the '543 (claims 17 and 31) and ' 628 (claim 17) Patents. The claim language appears substantially the same in all three claims, and reads (with the disputed phrase in bold):

'543 Patent:

17. The method of claims 1 or 2 wherein the mixture has a **pH of approximately 8.0.**

Britesmile proposes the construction: "pH between 7.6 and 8.4." Discus proposes the more limited construction: "pH of between 7.95 and 8.04." Neither the surrounding claim language nor the specification specifically addresses the meaning of "approximately 8.0."

Discus asserts that one of the factors the Court may consider in determining the meaning of "approximately" is the level of precision available to those working in the art. *See* Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed.Cir.1996). Relying on extrinsic evidence, Discus asserts that in 1995 the pH of a composition could be measured to an accuracy of 0.01 pH units. The Federal Circuit has cautioned, however, that it is rarely feasible to attach a precise limit to qualifiers such as "approximately" or "about." Instead, the quantitative terms can "usually be understood in light of the technology embodied in the invention." *Id*. Looking at the specification, the pH measurements are stated consistently to one decimal position. Moreover, the examples of embodiments of the invention discuss the pH levels in intervals of 0.5. The use of the qualifier "approximately" dictates that a precise value should not be assigned to the phrase. Nevertheless, looking at the term in the context of the claimed inventions, a variance of 0.4 in either direction is appropriate.

The Court adopts Britesmile's proposed construction and construes the term "pH of approximately 8.0" to mean: **pH between 7.6 and 8 .4.**

CONCLUSION

Based upon the analysis set forth above, the Court adopts the foregoing constructions of the disputed terms. The parties are ordered to submit a further joint case management report pursuant to Patent Standing Order para. 13 within 21 days of the filing of this Order.

IT IS SO ORDERED.

N.D.Cal.,2005.
Britesmile, Inc. v. Discus Dental, Inc.

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