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(54) **PROCEDE ET COMPOSITION SERVANT A BLANCHIR LES DENTS**

(54) **DENTAL BLEACHING COMPOSITION AND METHOD**

(57) Composition servant à blanchir les dents et présentant une amélioration de l'efficacité, ainsi qu'une diminution de la sensibilité, son procédé d'utilisation et trousse contenant les ingrédients servant à préparer cette composition. Cette dernière se présente sous la forme d'un gel dont le pH est entre 9 et 11, et contient un agent de blanchiment, tel que du peroxyde d'hydrogène, un matériau gélifiant inerte, tel que des composés de silice, un modificateur de pH, tel qu'hydroxyde de sodium, et un matériau inerte discret en particules capable d'absorber l'émission de lumière laser et de la retransmettre sous forme d'énergie thermique. On place cette composition de blanchiment sur les dents à blanchir, on l'expose à l'énergie laser et on la retire. On répète cette opération jusqu'à obtention du niveau souhaité de blanchiment. On applique ensuite du fluorure de sodium neutre aux dents blanchies pendant au moins dix minutes afin de limiter ou d'éliminer la sensibilité après blanchiment.

(57) A dental bleaching composition having enhanced effectiveness and reduced sensitivity, its method of use, and a kit containing the ingredients for making the composition. The dental bleaching composition is in the form of a gel with a pH of about 9 to 11 and comprises a bleaching agent such as hydrogen peroxide, an inert gelling material such as silica compounds, a pH modifier such as sodium hydroxide, and a discrete inert particulate material capable of absorbing the emitted laser light and retransmitting it as thermal energy. The dental bleaching composition is placed on the teeth to be bleached, exposed to laser energy, and removed. The process is then repeated until the desired amount of bleaching is achieved. Neutral sodium fluoride is then applied to the bleached teeth for at least 10 minutes to reduce or eliminate post-bleaching sensitivity.

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(54) Title: DENTAL BLEACHING COMPOSITION AND METHOD

(57) Abstract

A dental bleaching composition having enhanced effectiveness and reduced sensitivity, its method of use, and a kit containing the ingredients for making the composition. The dental bleaching composition is in the form of a gel with a pH of about 9 to 11 and comprises a bleaching agent such as hydrogen peroxide, an inert gelling material such as silica compounds, a pH modifier such as sodium hydroxide, and a discrete inert particulate material capable of absorbing the emitted laser light and retransmitting it as thermal energy. The dental bleaching composition is placed on the teeth to be bleached, exposed to laser energy, and removed. The process is then repeated until the desired amount of bleaching is achieved. Neutral sodium fluoride is then applied to the bleached teeth for at least 10 minutes to reduce or eliminate post-bleaching sensitivity.

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DENTAL BLEACHING COMPOSITION AND METHOD

Cross-Reference to Related Applications

This application is a continuation-in-part of U.S. Patent Application Serial No. 08/757,248, filed on November 27, 1996.

Field of the Invention

The present invention relates to dental bleaching compositions and methods, and more particularly to dental bleaching compositions and methods utilizing a laser to enhance the bleaching action. The invention more particularly relates to dental bleaching compositions and methods with enhanced removal of both extrinsic and intrinsic discolorants from the dentition and with reduced pain or sensitivity associated with the bleaching process.

Background of the Invention

Discolorations of the dentition are traditionally classified into two main categories, extrinsic and intrinsic. Extrinsic discolorations, or stains, are on the outer surface of the dentition and can be removed from the surface by dental instruments or polishing abrasives. Intrinsic discolorations, or stains, located within the crystalline matrix of the enamel and dentin and cannot be removed by the use of dental instruments or polishing abrasives.

Extrinsic discolorations or stains are usually superficial stains of the tooth surface resulting from the deposition of a film, pigments or calculus on the teeth. Many agents can cause such extrinsic discolorations including common substances such as coffee, tea, artificial food colorations, grapes, berries, smoking or chewing of tobacco, and the like. Stain intensity, and consequently ease of removal of the stains, are worsened by the penetration of the stain into tooth surface irregularities such as pits, cracks, grooves, exposed dentin, and bared root surfaces resulting from recession. The degree of difficulty of removal of the stain increases the deeper the penetration of the stain, with some stains penetrating to such a depth that the removal is

extremely difficult or virtually impossible using current methods of stain removal.

Intrinsic discolorations can have many causes of either an endogenous or exogenous origin and may occur during or after odontogenesis. During the process of creation of the teeth, referred to as odontogenesis, the teeth may become discolored from changes in the quality or quantity of enamel or dentin, or from incorporation of discoloring agents in the hard tissues, and may be caused by many diseases and medications, such as tetracycline. Post-eruption discolorations occur when discoloring agents enter the dental hard tissues from either the pulp cavity or tooth surface and can be caused by trauma, aging, metals, dental materials, and contact with or ingestion of certain foods and beverages.

A commonly practiced technique for removing discoloration is the practice of external bleaching, often with hydrogen peroxide. However, known bleaching agents are able only to remove discoloring agents located within five to seven microns from the enamel surface due to the high inorganic content and limited permeability of the enamel. Thus intrinsic discolorations and deeply penetrating extrinsic discolorations are left untouched.

Many attempts have been made over the years to find a bleaching system capable of removing intrinsic and deeply penetrating extrinsic stains. Chemical reagents that have been tried include hydrogen peroxide, oxalic acid, pyrozone (hydrogen peroxide and ethyl ether), muriatic acid, and chlorine compositions, as well as bleaching agents such as a 30% superoxol (30% hydrogen peroxide stabilized by reducing the pH to 4.0-5.0) or a pyrozone (30% hydrogen peroxide and ethyl ether) used in conjunction with heat from a light source, such as a tungsten lamp, or a heated instrument or bleaching paddle. The addition of heat to accelerate hydrogen peroxide's bleaching action has made such systems capable of reacting fast enough for in-office use. However, side effects due to the increased reactivity can be quite painful and include inflamed or burned gingiva and lips, as

well as significant post-bleaching tooth sensitivity.

In an effort to overcome these side effects, "cold bleaching" systems were developed. These systems used longer room temperature reaction times instead of shorter heat activated reaction times. In these cold bleaching systems, the hydrogen peroxide is thickened or gelled to allow the hydrogen peroxide to form a coating capable of remaining in contact with the teeth for extended period of time. Although the cold bleaching systems eliminated the side effects of the application of heat, a number of office visits were still required to achieve satisfactory results and post-bleaching sensitivity still occurred. Recently, as disclosed in U.S. Patent No. 5,645,428 to Yarborough, lasers have been used in a two-step dental bleaching process in which first an admixture of a bleaching agent and a catalyst are applied to the teeth and then exposed to an argon laser light to activate the bleaching agent followed by a second application of an admixture of a bleaching agent and a catalyst followed by exposure to a CO_2 laser. However, the use of the CO_2 laser adds considerable cost to the process as well as greatly increasing the chances incurring damage to the enamel surface on the teeth due to exposure to the CO_2 laser.

Summary of the Invention

It has now been discovered that the dental bleaching composition of the present invention can be used in conjunction with a laser to provide enhanced effectiveness of the bleaching action while reducing post-bleaching sensitivity.

The dental bleaching composition comprises a bleaching agent such as hydrogen peroxide, carbamine peroxide and the like; an inert gelling compound such as a silicon dioxide compound; a pH modifier such as sodium hydroxide; and a discrete inert particulate laser enhancing material such as beads having a color complementary to the color of the laser light. These materials are admixed to form a translucent or transparent gel with a pH of about 9 to 11, more preferably

from about 9.5 to about 10.5, and most preferably from about 10 to 10.5. The discrete particles are capable of absorbing the light energy from the wavelength of light emitted from the laser and retransmitting it as thermal energy. These discrete particles are dispersed throughout the bleaching composition so that the laser beam can pass through to the surface of the tooth while the particles absorb a portion of the light energy from the laser and retransmit it as thermal energy thus increasing the effectiveness of the bleaching composition.

The dental bleaching composition of the present invention is used in the process of the present invention by placing it on the tooth surfaces to be bleached to coat the area to be bleached. The coated tooth surfaces are exposed to laser energy, and then the coating is removed from the tooth surfaces, preferably by rinsing. The process is then repeated for one or more cycles until the desired degree of bleaching of the dental surface is achieved. Neutral sodium fluoride is then applied to the bleached teeth for at least 10 minutes to reduce or eliminate post-bleaching sensitivity.

A kit containing the ingredients allows single dose applications to be mixed immediately before use.

Detailed Description of the Invention

The present invention is directed to a novel dental bleaching composition and its method of use which results in enhanced bleaching action while reducing or eliminating post-bleaching sensitivity. The topical dental bleaching composition of the present invention comprises a gel formed from admixing a bleaching agent with an inert gelling compound. The pH of the gel is modified or adjusted at least 9.0 to reduce post-bleeding sensitivity. To enhance the effectiveness of the bleaching composition, discrete inert laser enhancing particles are dispersed throughout the composition.

The bleaching agent may be any bleaching agent suitable for use on dentition in living patients. Preferably the

bleaching agent hydrogen peroxide or carbamine peroxide. Other suitable bleaching agents may include sodium perborate, oxalic acid (for iron stains), chlorine (for silver and copper stains), and ammonia (for iodine-containing stains).

In the most preferred embodiment of the present invention, the bleaching agent is hydrogen peroxide in concentrations ranging from about 5% to about 70% by volume, more preferably from about 25% to about 60% by volume, and most preferably from about 35% to about 50% by volume. The amount of hydrogen peroxide present is about 90 to 95% by weight of the total mixture.

Any suitable inert gelling compound may be used that is capable of forming a gel or thickened mixture when admixed with the bleaching agent. Suitable compositions include silica compounds, sodium stearate, and long chain hydrocarbons such as Carbopol™, Trolamine™ and Polyox™. In a preferred embodiment of the present invention, an inert silica compound is used and suitable silica compounds include silicon dioxide, fumed silica and the like. Preferably the silica compound is in a finely divided form that enhances the gelling reaction with the bleaching agent, such as hydrogen peroxide. The preferred concentration of the silica gelling agent is approximately 5 to 10% by weight.

Bleaching agents, such as hydrogen peroxide, are concentration-dependant pulpal irritants. The higher the concentration of bleaching agent placed on the surface of a tooth, the more rapidly the concentration of the bleaching agent rises within the enamel and dentin of the tooth. Even at lower concentrations, bleaching agents can irritate the pulp causing pulpitis and at higher concentrations, can cause pulpal death.

One embodiment of the present invention is directed to the discovery that even with very high concentrations of hydrogen peroxide and other bleaching agents, post-bleaching tooth and dental sensitivity can be significantly decreased by maintaining hydration of the dental tissues during the bleaching process and thus eliminating pulpitis and its

attendant sensitivity. It has been discovered that there is a significant difference in pain both during and after bleaching teeth with a hydrogen peroxide/silicon dioxide gel and an argon laser when the teeth were rinsed with water every 3 to 5 minutes during the bleaching procedure to keep them hydrated. In these tests, patients had a hydrogen peroxide and silicon dioxide gel placed on six maxillary anterior teeth, canine to canine. The teeth were exposed, in turn, to 40 seconds of argon laser light per tooth.

On three teeth, the bleaching gel was wiped away with a cotton gauze and on the other three teeth, the bleaching gel was rinsed away and the teeth were bathed in water for approximately 20 seconds. The bleaching gel was then replaced and the cycle was repeated for a total of six cycles. Patients reported significantly less pain during and after the bleaching procedure on the teeth that were hydrated. When the sides were switched and the teeth that had been bathed in water were wiped clean instead, while the teeth that were wiped were hydrated, the patients reported that the teeth that were sensitive had switched as well.

It has unexpectedly been discovered that adjusting or modifying the pH of the bleaching composition to between 9.0 and 11.0, more preferably between 9.5 and 10.5, and most preferably between 10.0 and 10.5, results in a significant reduction in post-bleaching sensitivity. Any suitable pH modifier can be used that does not adversely affect the bleaching action of the bleaching agent such as disassociation of a peroxide bleaching agent. In one embodiment of the present invention, sodium hydroxide (NaOH) or sodium polysilicate is used to adjust the pH.

In a preferred embodiment of the present invention, a laser capable of increasing the bleaching action of a bleaching agent on a tooth surface, such as an argon laser, is used to enhance the bleaching action of the dental bleaching composition of the present invention. Theoretically, the laser light enhances the speed by which enamel and dentin can be bleached by any or all of the

following mechanisms: i) lowering the energy needed to break down the stain molecules within the teeth, ii) pushing the bleaching gel into the tooth more rapidly, and iii) interacting with the bleaching gel to enhance its reactivity. It has been discovered that teeth coated with a hydrogen peroxide and fumed silica gel and exposed to argon laser light bleach lighter than teeth of the same shade bleached with the gel alone. This effect is dependent on the strength of the argon laser, with a laser yielding a power density of 550-700 milliwatts/cm^2 bleaching the coated tooth surfaces more effectively than a laser yielding a power density of 350-550 milliwatts/cm^2 but at the cost of increased sensitivity during and following the bleaching process. This may be due to one or both of the following mechanisms. i) The laser energy "pushes" the hydrogen peroxide into the tooth more rapidly -- the concentration of hydrogen peroxide at any distance from the surface of the tooth may be greater when the tooth is bathed in argon laser light than in the absence of the laser. ii) The laser energy may contribute directly to pulpal irritation.

In a preferred embodiment of the present invention, the bleaching action of the dental bleaching composition is enhanced by the inclusion into the bleaching composition of a discrete inert particulate material that absorbs the wavelength of light emitted by the laser. In one embodiment of the present invention, the discrete inert particulate matter is pigmented or colored in a color complement to the laser light, thus resulting in efficient absorption of the laser light wavelength. For example, an argon laser utilizes a blue light with a wavelength in the range of 470 nm to 520 nm. The color complement to blue is orange, and thus an orange or red-orange particulate material that reflects light in the 600 nm to 650 nm range and absorbs at all other wavelengths would enhance the action of the laser and would be preferred since orange is the color complement to blue. Other colors or compositions that absorb at the wavelength that laser light is emitted are also suitable. For example,

a black particulate material would absorb all wavelengths of emitted light. Particulate material made from compositions of matter that absorb emitted laser light in the desired wavelength ranges are also suitable. For example, an inert plastic material that absorbs light at a of 470 nm to 520 nm can be used as the discrete particulate material of the present invention for use with an argon laser.

There are no studies that show hydrogen peroxide or other bleaching agents are activated or made more reactive directly by exposure to laser energy. However, it has been discovered that the inclusion of an inert compound that absorbs the emitted laser light in the form or 100-200 micron particles makes hydrogen peroxide and other bleaching agents more reactive when exposed to an intense light, such as that given off by an argon laser. As discussed above, orange is the color complement to blue, and as such, absorbs the energy of the blue argon laser light in an efficient manner allowing it to be retransmitted as thermal energy. In the micro-environment surrounding the orange particles, this increase in thermal energy makes the hydrogen peroxide more reactive.

The discrete inert colored particulate material can be made of any suitable material that will not react with the hydrogen peroxide or other bleaching agent and that will not leach its color into the tooth surface during the bleaching process. Suitable materials include colored or coated porcelain, ceramic, thermoplastic or polymeric resins such as acrylic resins, cellulosic resins, ceramic fiber compounds, fluoroplastic resins, polyamide resins, polycarbonate resins, phenolic resins, polyethelene resins, polyester resins, polymethylpentene resins, polyoxymethylene resins, polyphenylene resins, polypropylene resins, polystryrene resins, polyvinyl resins, nitrile resins, terephthalic resins, or glass fiber compounds. However, other types of plastics and polymeric materials known to those in the art may be used provided that they do not react. The particles can be coated or colored by any suitable means

and such coating and coloring processes are well known in the art.

In an alternative embodiment of the present invention, the discrete laser enhancing particles are made of a material that absorbs the wavelength of the emitted laser light and retransmits it as thermal energy. Suitable materials are known to those of ordinary skill in the art.

The size of the particles can vary and preferably range from about 50 microns to about 400 microns, more preferably from about 75 microns to about 200 microns, and most preferably from about 90 microns to 125 microns.

The discrete particulate material enhances the laser's action by increasing the thermal energy, and thus the reactivity of the bleaching agent. The amount or density of the particles in the bleaching gel is sufficient to allow the laser to enhance the reactivity of the hydrogen peroxide. However, the particulate density or amount is not so great that it blocks the laser light from reaching the surface of the tooth. As described above, it is necessary for the laser light to reach the tooth in order to enhance the bleaching action of the bleaching agent since this appears to be the more important part and thus the density of the particulate matter needs to be adjusted accordingly.

In another embodiment of the present invention, post-bleaching sensitivity is further reduced by the application of neutral sodium fluoride to the bleached teeth for at least ten minutes. Fluoride has been used in dentistry to reduce sensitivity for many years. Often, when the root surface of teeth are exposed to the oral cavity due to gingival recession, these teeth become sensitive to hot, cold and sometimes sweets. Fluoride has been shown to reduce this sensitivity by combining with the crystalline structure of the tooth to form fluorapatite and by blocking dentinal tubuals. It has been discovered that the application of neutral sodium fluoride for at least ten minutes following bleaching teeth with a gel of 50% hydrogen peroxide, fumed silica and sodium hydroxide, in conjunction with exposure to

an argon laser, significantly reduces or eliminates the intense pain that other wise results. This post bleaching pain usually has an onset of about 2 hours post-bleaching and lasts for 2 or more days. When neutral sodium fluoride is applied to the teeth for 5 minutes post bleaching, the pain level is often diminished and lasts for only 8 to 12 hours. When neutral sodium fluoride is applied to the bleached teeth for a full 10 minutes after bleaching is completed, post-bleaching sensitivity is almost completely eliminated.

The dental bleaching composition of the present invention can be supplied to dental practitioners in the form of a kit containing ingredients sufficient for either individual or multiple treatments. The ingredients can be supplied individually in separate containers or vials, or can have multiple ingredients premixed so that the hydrogen peroxide containing mixture can be admixed by the dental professional with the silicon compound at the point of use. In one embodiment, it is contemplated that the dental professional will be supplied with a kit containing the ingredients making up the bleaching composition of the present invention so that the bleaching composition can be mixed "chairside" and immediately used. For example, the kit may contain 2 premeasured containers, one containing a bleaching agent such as hydrogen peroxide with glycerin, and the other containing a pH modifier such as sodium hydroxide or sodium polysilicate, with a premixed quantity of the inert gelling agent such as silica or fumed silica and the discrete laser enhancing particulate matter. For an argon laser, the particulate matter is preferably orange. All items are packaged with a protocol by which safe and effective use of the materials can be achieved.

The present disclosure includes that contained in the appended claims as well as that of the foregoing description. Although this invention has been described in its preferred form with a certain degree of particularity, it is understood that the present disclosure of the preferred form has been made only by way of example and that numerous changes in the

details of construction and the combination and arrangement of parts may be resorted to without departing from the spirit and scope of the invention.

What is claimed:

1. A topical dental bleaching composition for use with a laser, said composition comprising
a bleaching agent
an inert gelling agent for forming a gel with said bleaching agent,
a plurality of discrete laser enhancing particles, and
a pH modifier.

2. The dental bleaching composition of claim 1 wherein said discrete inert laser enhancing particles absorb a portion of the light energy emitted by the laser and retransmit it as thermal energy.

3. The dental bleaching composition of claim 2 wherein laser light is absorbed by means of the color of the particles, the composition of the particles, or by combinations thereof.

4. The dental bleaching composition of claim 1 wherein said discrete laser enhancing particles are a complementary color to the color of the light emitted by the laser.

5. The dental bleaching composition of claim 2 wherein said particles have a size from about 50 to about 400 microns.

6. The dental bleaching composition of claim 5 wherein said particles have a size from about 75 to about 200 microns.

7. The dental bleaching composition of claim 6 wherein said particles have a size from about 90 to about 125 microns.

8. The dental bleaching composition of claim 3 wherein

said particles are coated with the color.

9. The dental bleaching composition of claim 3 wherein the particles contain the color dispersed throughout the particles.

10. The dental bleaching composition of claim 1 for use with a laser emitting a blue light, wherein said particles are orange glass beads having a diameter from about 90 to about 125 microns.

11. The dental bleaching composition of claim 3 wherein said particles are color coated beads having a diameter from about 90 to about 125 microns.

12. The dental bleaching composition of claim 2 wherein the particles are made of a material selected from the group consisting of colored or coated porcelain, ceramic, thermoplastic or polymeric resins such as acrylic resins, cellulosic resins, ceramic fiber compounds, fluoroplastic resins, polyamide resins, polycarbonate resins, phenolic resins, polyethelene resins, polyester resins, polymethylpentene resins, polyoxymethylene resins, polyphenylene resins, polypropylene resins, polystryrene resins, polyvinyl resins, nitrile resins, terephthalic resins, and glass fiber compounds.

13. The dental bleaching composition of claim 2 wherein said particles are present in an amount sufficient to enhance the activity of the bleaching agent.

14. The dental bleaching composition of claim 2 wherein said particles are present in an amount such that light from the laser can penetrate the bleaching composition to reach the surface of the tooth.

15. The dental bleaching composition of claim 1 wherein

the bleaching agent is selected from the group consisting of hydrogen peroxide, carbamine peroxide, sodium perborate, oxalic acid, chlorine, and ammonia.

16. The dental bleaching composition of claim 1 wherein the bleaching agent is hydrogen peroxide.

17. The dental bleaching composition of claim 16 wherein said hydrogen peroxide preferably has a concentration from about 5% to about 70% by volume.

18. The dental bleaching composition of claim 17 wherein said hydrogen peroxide more preferably has a concentration from about 25% to about 60% by volume.

19. The dental bleaching composition of claim 18 wherein said hydrogen peroxide more preferably has a concentration from about 35% to about 50% by volume.

20. The dental bleaching composition of claim 1 wherein the pH is from about 9 to about 11.

21. The dental bleaching composition of claim 20 wherein the pH is from about 9.5 to about 10.5.

22. The dental bleaching composition of claim 1 wherein the pH is from about 10.0 to about 10.5.

23. The dental bleaching composition of claim 20 wherein the pH modifier is selected from the group consisting of sodium hydroxide and sodium polysilicate.

24. The dental bleaching composition of claim 1 wherein said inert gelling agent is selected from the group consisting of silica compounds, sodium stearate, and long chain hydrocarbons such as Carbopol™, Trolamine™ and Polyox™

25. The dental bleaching composition of claim 24 wherein said inert gelling agent is a silicon dioxide compound.

26. The dental bleaching agent of claim 25 wherein said inert gelling agent is a mixture of silicon dioxide and glycerin.

27. The dental bleaching agent of claim 21 wherein said inert gelling agent is fumed silica.

28. A dental bleaching composition with reduced post-bleaching sensitivity, said composition comprising:

hydrogen peroxide;

a thickening agent that forms a gel when mixed with said hydrogen peroxide;

a pH modifier to adjust the pH of the composition to about 9.5 to about 10.5.

29. The dental bleaching composition of claim 28 wherein said pH modifier is selected from the group consisting of sodium hydroxide and sodium polysilicate.

30. A method for bleaching teeth comprising the steps of:

forming a bleaching gel by admixing a bleaching agent with a thickening agent, a pH modifier and discrete inert laser enhancing particles;

applying said bleaching gel to the surface of the teeth to be bleached;

exposing the bleaching gel coated tooth surface to a laser.

removing the bleaching gel from the tooth surface.

31. The method of claim 30 wherein the process is repeated until the desired degree of bleaching of the teeth

is reached.

32. The method of claim 31 further comprising the step of applying sodium fluoride to the bleached teeth for at least 10 minutes.

33. The method of claim 30 wherein said discrete inert laser enhancing particles are complementary in color to the color of said laser.

34. The method of claim 33 wherein said particles have a size from about 90 to 200 microns.

35. The method of claim 33 wherein said laser is an argon laser and said particles are orange.

36. The method of claim 35 wherein said particles are glass beads having a diameter from about 90 to 200 microns.

37. The method of claim 35 wherein said particles are orange color coated beads having a diameter from about 90 to 200 microns.

38. The method of claim 30 wherein said particles are present in an amount sufficient to enhance the activity of the hydrogen peroxide.

39. The method of claim 30 wherein said particles are present in an amount such that light from the laser can penetrate the bleaching composition to reach the surface of the tooth.

40. The method of claim 30 wherein said hydrogen peroxide has a concentration from about 5% to about 70% by volume.

41. The method of claim 40 wherein said hydrogen

peroxide has a concentration from about 35% to about 60% by volume.

42. The method of claim 30 wherein the pH is from about 9 to about 11.

43. The method of claim 42 wherein the pH is from about 9.5 to about 10.5.

44. The method of claim 30 wherein the pH is from about 10.0 to about 10.5.

45. The method of claim 42 wherein the pH modifier is selected from the group consisting of sodium hydroxide and sodium polysilicate.

46. The method of claim 30 wherein the laser is an argon laser.

47. The method of claim 46 wherein the power density of said argon laser is from about 200 milliwatts/cm^2 to about 700 milliwatts/cm^2.

48. The method of claim 46 wherein tooth sensitivity is further reduced by using a power density of about 200 milliwatts/cm^2 to about 500 milliwatts/cm^2.

49. The method of claim 46 wherein reactivity of the hydrogen peroxide is increased by using a power density of about 550 milliwatts/cm^2 to about 700 milliwatts/cm^2.

50. The method of claim 30 with further reduced tooth sensitivity, said method further comprising the step of hydrating the tooth surface and surrounding dental tissue by rinsing the tooth surface following or during the step of removing the bleaching gel from the tooth surface.

51. A method for enhancing the reactivity of a hydrogen peroxide containing dental bleaching composition comprising the steps of:

mixing discrete inert laser enhancing particles with said hydrogen peroxide containing dental bleaching composition to form a laser enhanced bleaching mixture;

coating the tooth surface to be bleached with said mixture;

exposing said coated tooth surface to laser light; and

removing said mixture from said tooth surface.

52. A method for decreasing sensitivity during dental bleaching, said method comprising the steps of:

forming a dental bleaching composition;

modifying the pH of said dental bleaching composition to about 9.5 to about 10.5;

applying said pH modified dental bleaching composition to the surface of the teeth;

allowing the bleaching composition to react with the surface of the teeth to bleach the teeth;

removing said reacted bleaching composition from the surface of the teeth;

hydrating the surface of the teeth and the surrounding dental tissue; and

applying sodium fluoride to the surface of the teeth for at least 10 minutes.

53. A dental bleaching system for use with a laser, said system comprising:

a hydrogen peroxide solution having a concentration of about 35% to 60% by volume;

a pH modifying agent selected from the group consisting of sodium hydroxide and sodium polysilicate;

a gelling agent selected from the group consisting of an inert silicon compound capable of forming a gel when admixed with said hydrogen peroxide, fumed silica, a mixture of a silicon dioxide compound and glycerin, and mixtures

thereof; and

discrete inert colored particles in a color complementary to the color of the laser.

54. The dental bleaching system of claim 53 for use with an argon laser wherein said discrete particulate material is orange.

55. A kit for preparing a dental bleaching composition for use with a laser, said kit comprising:

a hydrogen peroxide solution having a concentration of about 35% to 60% by volume;

a pH modifying agent selected from the group consisting of sodium hydroxide and sodium polysilicate;

an inert silica compound capable of forming a gel when admixed with said hydrogen peroxide;

glycerin; and

discrete inert colored particles in a color complementary to the color of the laser.

56. The kit of claim 55 further comprising a first and a second container wherein

said first container contains said hydrogen peroxide and said glycerin and

said second container contains said pH modifying agent, said inert silica compound, and said discrete inert colored particles.

57. The kit of claim 55 for use with an argon laser wherein said discrete inert colored particles are orange.

PCT CHECKLIST

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8. Drawings submitted : Yes (No)
9. **Chapter I or Chapter (II) - Amendment under Article 19 or Article 34**
   Preliminary Examination Report : Missing __ Yes ✓
   Publication as filed ✓ Amendment, entered ____
   Abstract 1 **Specification** 1-11 **Claims** 1-57 **Drawings:** ✓ (Pages) ✓ (Figs)
   Sequence listing ✓
10. **Agent's Code** : 03157
11. Pub. No: WO9 8/23219
12. **Formalities - Submission of Information:**
    Cdn. Rep. & Agent : (Yes) No
    ~~**Evidence included** : Yes No~~
    Change of name (IB306) : Yes (No)
    Name & address of inventor : (Yes) No
13. PCT. Language of (Pamphlet) : (English) French Foreign
14. ~~Agent's Copy~~ : English French
    As Filed: ____ Amended: ____

R. 8.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Canadian Patent Office
The Commissioner of Patents
50 Victoria Street
Ontario K1A 0C9
CANADA

in its capacity as elected Office

Date of mailing (day/month/year) 15 June 1998 (15.06.98)	
International application No. PCT/US97/21273	**Applicant's or agent's file reference** 23200X-PC
International filing date (day/month/year) 26 November 1997 (26.11.97)	**Priority date** (day/month/year) 27 November 1996 (27.11.96)
Applicant SIBNER, Jeffrey, A.	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

21 May 1998 (21.05.98)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer A. Addae-Ruesch Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

2083778

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 23200X-PC	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US97/21273	International filing date *(day/month/year)* 26 NOVEMBER 1997	Priority date *(day/month/year)* 27 NOVEMBER 1996
International Patent Classification (IPC) or national classification and IPC IPC(6): A61C 5/00; and US Cl.: 424/53; 433/215		
Applicant SIBNER, JEFFREY A.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

AS FILED / TEL QUE DEPOSE

Date of submission of the demand	Date of completion of this report
21 MAY 1998	27 JULY 1998
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CARY O'CONNOR Telephone No. (703) 308-2701

Form PCT/IPEA/409 (cover sheet) (January 1994)*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US97/21273

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

[X] the international application as originally filed.

[X] the description, pages 1-11 , as originally filed.
pages NONE , filed with the demand.
pages NONE , filed with the letter of _____
pages _____ , filed with the letter of _____

[X] the claims, Nos. 1-57 , as originally filed.
Nos. NONE , as amended under Article 19.
Nos. NONE , filed with the demand.
Nos. NONE , filed with the letter of _____
Nos. _____ , filed with the letter of _____

[X] the drawings, sheets/~~fig~~ NONE , as originally filed.
sheets/~~fig~~ NONE , filed with the demand.
sheets/~~fig~~ NONE , filed with the letter of _____
sheets/~~fig~~ _____ , filed with the letter of _____

2. The amendments have resulted in the cancellation of:

[X] the description, pages NONE .
[X] the claims, Nos. NONE .
[X] the drawings, sheets/~~fig~~ NONE .

3. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US97/21273

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	1-57	YES
	Claims	NONE	NO
Inventive Step (IS)	Claims	1-57	YES
	Claims	NONE	NO
Industrial Applicability (IA)	Claims	1-57	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-27 and 53-57 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest a bleaching composition comprising a bleaching agent, and a plurality of discrete laser enhancing particles.

Claims 30-52 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest a method for bleaching teeth wherein a bleaching gel, comprising, inter alia, discrete inert laser enhancing particles, is applied to the teeth. The prior art also does not teach a method of decreasing sensitivity during dental bleach comprising the steps of hydrating the surface of the teeth and surrounding tissue, and applying sodium fluoride to the teeth for at least ten minutes.

Claims 28 and 29 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest a dental bleaching composition comprising hydrogen peroxide, and a pH modifier to adjust the pH of the composition to about 9.5 to about 10.5.

---------- NEW CITATIONS ----------
NONE

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21273

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61C 5/00
US CL :424/53; 433/215

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/49, 53; 433/215

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,E	US 5,713,738 A (YARBOROUGH) 03 February 1998, entire document.	1-57

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 FEBRUARY 1998	11 MAR 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CARY O'CONNOR Telephone No. (703) 308-2701

Form PCT/ISA/210 (second sheet)(July 1992)★