



(51) International Patent Classification:
A61C 19/06 (2006.01)

(21) International Application Number:
PCT/US2013/039693

(22) International Filing Date:
6 May 2013 (06.05.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/647,632 16 May 2012 (16.05.2012) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,

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(54) Title: DENTAL DEVICE FOR DELIVERING AN ORAL CARE SUBSTANCE TO ORAL SURFACES

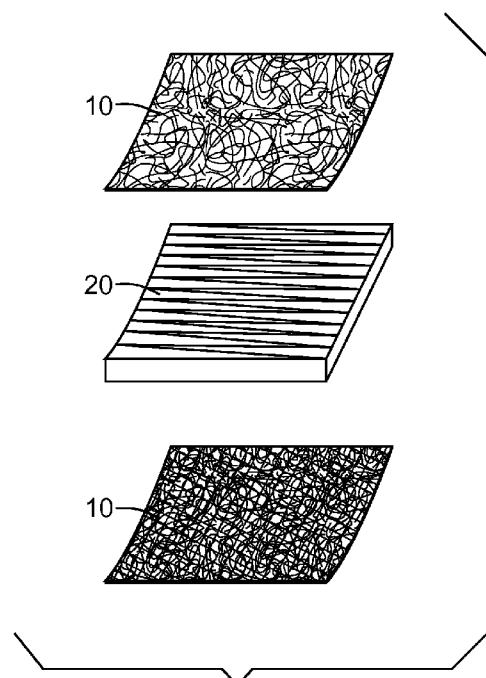


FIG. 1

(57) Abstract: Dental devices for the delivery of oral care substances or compositions, and methods for applying an oral care substance to a patient's oral hard and soft tissues are described. In one embodiment, the dental device comprises a layer of an orally acceptable malleable material and a non-woven material in contact with at least a portion of one side of the malleable material layer.



EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

— *as to the applicant's entitlement to claim the priority of
the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii))*

Background

Dental delivery devices are used for delivering oral care substances to oral surfaces including teeth and oral tissues. Traditionally, there are two types of dental delivery devices. One type of delivery device is a stock device that is pre-fabricated into a variety of standard sizes. The other type of delivery device is a customized device that is made by molding over an individual's teeth model and is custom-fitted to an individual's dental arches.

Summary

The present invention provides dental devices for the delivery of oral care substances or compositions, and methods for applying an oral care substance to a patient's dental arch and oral tissues. The dental device and method described herein can provide various benefits to the users over traditional dental devices. Traditional dental devices are difficult to handle and uncomfortable for the patient during the use. Unlike a traditional dental device, the dental device of the present invention is malleable and thus can be customized for each patient. In addition, the dental device is thin and more comfortable for a patient during treatment.

In one embodiment, a dental device is described. The dental device comprises a layer of an orally acceptable malleable material, the malleable material layer shaped to envelop a dental arch and/or gingiva, and a non-woven material in contact with at least a portion of one side of the malleable material layer.

In another embodiment, a method for applying an oral care substance to a patient's oral hard and soft tissues is described. The method comprises: (1) providing a dental device, the dental device comprising a layer of an orally acceptable malleable material, the malleable material layer sized to cover a dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable material layer; (2) placing the dental device in contact with a patient's dental arch and/or gingiva; (3) conforming the dental device to fit to the dental arch and/or gingiva; (4) removing the dental device from the dental arch and/or gingiva; (5) applying the oral care substance to the dental device; and (6) treating the dental arch and/or gingiva with the oral care substance.

In another embodiment, a method for applying an oral care substance to a patient's oral hard and soft tissues is described. The method comprises: (1) providing a dental device, the dental device comprising a layer of an orally acceptable malleable material, the malleable material layer sized to cover a dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable material layer, wherein the dental device is preformed to fit the overall shape of the dental arch and/or gingiva; (2) applying an oral care substance to the dental device; and treating the dental arch and/or gingiva with the oral care substance.

In a further embodiment, a method for applying an oral care substance to a patient's oral hard and soft tissues is described. The method comprises: (1) providing a dental device, the dental device

comprising, a layer of an orally acceptable malleable material, the malleable material layer sized to cover a dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable material layer, wherein the dental device is preloaded with the oral care substance; (2) placing the dental device in contact with the dental arch and/or gingiva; (3) conforming the dental device to fit to the dental arch and/or gingiva; and (4) treating the dental arch and/or gingiva with the preloaded oral care substance.

In another embodiment, a method for applying an oral care substance to a patient's oral hard and soft tissues is described. The method comprises: (1) providing a dental device, the dental device comprising, a layer of an orally acceptable malleable material, the malleable material layer sized to cover a dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable material layer, wherein the dental device is preformed to fit the overall shape of the dental arch and/or gingiva and wherein the dental device is preloaded with the oral care substance; and (2) treating the dental arch and/or gingiva with the preloaded oral care substance.

Brief Description of the Drawings

Fig. 1 is a perspective view of a method of making a layered configuration comprising a layer of an orally acceptable malleable material and a non-woven material in contact with at least a portion of opposing sides of the malleable material layer.

Fig. 2A is a perspective view of a single arch configuration dental device.

Fig. 2B is a perspective view of a dual-arch configuration dental device.

Fig. 3A is a perspective view of a method of making a performed dental device by molding around a full arch typodont model.

Fig. 3B is a perspective view of a performed dental device.

Fig. 4 is a perspective view of a dental device preloaded with the oral care substance.

Detailed Description

Presently described are dental devices for the delivery of oral care substances or compositions, and methods for applying an oral care substance to a patient's hard and soft oral tissues.

Hard and soft oral tissues include, but not limited to, dental arch, gingiva, and hard palate.

In one embodiment, a dental device is described. The dental device generally comprises a layer of an orally acceptable malleable material and a non-woven material in contact with at least a portion of one side of the malleable material layer. Alternatively, dental device may comprise a woven material.

In some embodiments, the non-woven material may be in contact with at least a portion of one side of the malleable material layer.

Alternatively, one or more non-woven materials may be in contact with at least a portion of opposing sides of the malleable material layer, forming a sandwich configuration, as shown in FIG. 1. In some embodiments, the non-woven materials in contact with opposing sides of the malleable material layer may be similar. In other embodiments, the non-woven materials in contact with opposing sides of the malleable material layer may be dissimilar. For example, the non-woven material in contact with one

side of the malleable material layer is different than the non-woven material in contact with opposite side of the malleable material layer.

It is found that the non-woven material helps to provide structural integrity to the dental device and to eliminate the sticky feeling from the malleable material layer. The non-woven material may also serve as a reservoir for the oral care substance that can range in viscosity from a low viscosity fluid to a gel-like substance. The non-woven material also helps to prevent an oral care substance, if it is a liquid or fluid gel, from being excessively squeezed out from between the dental device and the teeth surfaces when the device pressed against the teeth, providing a controlled release or dispensing of the oral substance.

As shown in FIG. 2A and 2B, suitably, in some embodiments, the dental device may have tab 30 extending outwardly from a central portion of the device in order to facilitate gripping by the user. Such a tab may be used to facilitate the user in manipulating (e.g. placing, removing, applying) the dental device.

Suitable shapes and sizes of the dental device of the invention will now be discussed. In some embodiments, the size of the dental device may be such that it can cover a full dental arch and/or gingiva. In some embodiments, the dental device may generally be planar. As shown in FIG. 2A, in other embodiments, the dental device may be suitably of a single arch flat sheet, of a length sufficient that when placed against the dental arch it extends across the full dental arch. Alternatively, the dental device may be preformed and contoured so as to fit the overall shape of a dental arch and/or gingiva. Further, as will be explained in detail herein, the dental device may be configured to be instantly fitted to a particular person's dental arch and/or gingiva. In some embodiments, the dental device may be partially adapted to a generic arch shape. The dental device may be universal so as to fit the dental arch of practically any person. As is generally understood, the dental device of the present invention may comprise a plurality of different sizes as to fit persons having different dental arch sizes such as, for example, children and adults.

As shown in FIG. 2B, in some embodiments, the dental device may be of a dual arch flat sheet. The dental device has a first arch 40 extending in a curved configuration extending from a first end to a second end, and an opposing second arch 50 extending in a curved configuration extending from a first end opposite the first end of the first arch to a second end opposite the second end of the first arch.

In some embodiments, the dental device may be modified (e.g. molded, adapted, trimmed, cut, torn, bent, or folded) to a desired size. For example, a preformed dental device may be provided to the dentist in the desired semi-finished shape (a first shape), which can then be modified for custom in a person (a second shape).

In general, the thickness of the layer of malleable material may be selected to produce a dental device having a desired level of strength, rigidity, resilience, and malleability. In some embodiments, the malleable material layer may have a thickness ranging from about 1 mm to about 5 mm, from about 1 mm to about 4 mm, or from about 1 mm to about 3 mm. In other embodiments, the malleable material layer may have a thickness of about 2mm.

The layer of an orally acceptable malleable material may comprise any malleable material that is capable of being shaped and adapted, for example, to a patient's teeth or dental arches, under a humanly applied pressure. The orally acceptable malleable material should be sufficiently malleable to enable such adaption to the teeth or dental arches surface.

As used herein, "malleable" means that the material may be easily deformed by the user using finger or hand pressure, below or at body temperature, so as to fit the device to the overall shape of a patient's teeth and/or gingiva, preferably also being capable of being deformed into the gaps between the patient's teeth. Typically a dental device comprising of malleable material should be plastically deformable under the application of a pressure of less than 250,000 pascals, e.g. to allow the device to be deformed to fit the contours of the patient's teeth and/or oral tissues.

In some embodiments, the adaption of the malleable material may be non-permanent in which the material keeps its malleability and can be formed into another shape under a moderate force (e.g., a force that ranges from finger pressure to the amount of force applied when biting).

The malleable material may comprise a polymeric compound, a wax, a rubber, or a mixture thereof.

In some embodiments, the malleable material may comprise a polymeric compound, such as described in U.S. Patent Application Publication No. 2006/009950. Examples of suitable polymeric compounds include polysaccharides (e.g., starches and starch derivatives, cellulose-derivatives such as sodium carboxymethyl cellulose or "Na-CMC"), and water-soluble synthetic polymers (e.g., 2-acrylamido-2-methyl-propanesulfonic acid or "poly AMPS", polyvinyl pyrrolidone or "PVP," polyvinyl alcohol or "PVA," hydroxypropyl cellulose or "HPC," polyethylene oxide or "PEO," polyacrylic acid or "PAA," and carboxylic acid polymers such as the Carbopols and Carbomers available from B. F. Goodrich); polypeptides; and natural gums such as xanthan gum, karaya gum, and gelatin.

In some embodiments, the malleable material may comprise a wax (e.g. paraffin or microcrystalline waxes).

Paraffin waxes are low molecular weight straight chain hydrocarbons. These waxes typically have melting points ranging from about 48° C. to about 75° C. and molecular weights ranging from about 300 to about 1400 g/mol. The paraffin waxes can be produced by the distillation of crude oil, or can be synthesized, for example by Fischer-Tropsch synthesis.

Microcrystalline waxes are flexible and amorphous-like in appearance, and are more elastic and have smaller and thinner crystals than the paraffin waxes. The molecular weight of microcrystalline waxes is typically about 580-700 g/mol, with the average molecule containing 41-50 carbon atoms. Microcrystalline waxes generally have melting points higher than the paraffin waxes. In some embodiments, microcrystalline waxes have melting points of about 20° C. to about 60° C. In other embodiments, microcrystalline waxes have melting points of about 37° C. Although straight chain hydrocarbons may exist in the microcrystalline waxes, the microcrystalline waxes contain a higher percentage of branched chain hydrocarbons and some ring-type compounds.

In some embodiments, the malleable material may comprise oil-filled thermoplastic elastomeric rubbers (e.g. styrene/rubber/styrene block copolymers), which may also contain waxes, liquid rubbers, tackifiers, antioxidants, colorants, fillers, and other adjuvants.

One exemplary material can comprise 70 to 95 parts by weight of mineral oil dispersed in 5 to 30 parts by weight of thermoplastic elastomer.

The term mineral oil, as used herein, refers to any of various light hydrocarbon oils, especially distillates of petroleum. Typically, the mineral oil is a white mineral oil although other mineral oils may be used. White mineral oils are generally colorless, odorless, tasteless mixtures of saturated paraffinic and naphthenic hydrocarbons that span a viscosity range of 50-650 Saybolt Universal Seconds (5 to 132 centistokes) at 100°F (38°C). Nearly chemically inert, white mineral oils are essentially free of nitrogen, sulfur, oxygen and aromatic hydrocarbons. Representative oils include Kaydol, Sempitol 350 (both available from Sonneborn Refined Products B.V., Amsterdam, The Netherlands.), and crystal 350 (available from STE Oil company of San Marcos, TX). In an alternative embodiment, the mineral oil may be replaced fully or in part by another petroleum based oil, a vegetable oil, silicone oil, or a modified version of either of these two oil types.

Suitable thermoplastic elastomers include styrene-rubber-styrene (SRS) triblock copolymers, or mixtures of SRS triblocks and styrene-rubber (SR) diblock copolymers. Exemplary styrene-rubber-styrene triblock copolymers include styrene-butadiene-styrene (SBS), styrene-isoprene-styrene (SIS), and partially or completely hydrogenated derivatives thereof, such as styrene-ethylene/butylene-styrene (SEBS), styrene-ethylene/propylene-styrene (SEPS), styrene-ethylene/ethylene/propylene-styrene (SEEPS), and combinations thereof. Examples of commercially available suitable SEBS block copolymers for use in the exemplary sealant material include trade designated "KRATON G-1651" and "KRATON G-1633" Block Copolymers, both of which are commercially available from Kraton Polymers (Houston, TX). Examples of commercially available suitable SR diblock copolymers include trade designated "KRATON G-1701" and "KRATON G-1702" Block Copolymers both of which are commercially available from Kraton Polymers (Houston, TX), and "SEPTON S 1020" High Performance Thermoplastic Rubber which is commercially available from Kuraray Company (Tokyo, Japan). An exemplary commercially available suitable SEPS and SEEPS block copolymers for use in the exemplary material include trade designated "SEPTON S 4044" "SEPTON S 4055" "SEPTON S 4077" or "SEPTON S 4099" High Performance Thermoplastic Rubber which are commercially available from Kuraray Company (Tokyo, Japan). Additionally, suitable vinyl-rich block copolymers for use in the exemplary material include "HYBRAR 7125" and "HYBRAR 7311" High Performance Thermoplastic Rubbers, which are also commercially available from Kuraray Company (Tokyo, Japan). A suitable maximum concentration of the block copolymer in the gel material is about 30% by weight, based on the entire weight of gel sealant material.

Additional polymer additives could include liquid rubber materials, and waxes. An example of a liquid rubber additive would be the family of polybutene oligomers/polymers available as Indopol from Ineos of League City, TX. Suitable waxes include synthetic waxes, petroleum derived waxes, and natural

waxes like those derived from plants and animals. The synthetic and petroleum derived waxes include paraffinic waxes, polyethylene and polypropylene waxes, and derivatives of these, including partially oxidized paraffinic waxes, and copolymer waxes with maleic anhydride. Representative of some of these materials include the following waxes available from Honeywell of Minneapolis MN, A-C 9, A-C 925, A-C 207, A-C 395, A-C 950P, A-C 1172, A-C 307; and from Eastman: Epolene C-16.

Suitable fillers and additives could include glass beads or bubbles, polymer beads, inorganic solids like talc, calcium carbonate, flame retardant materials like hydrated aluminum oxides or magnesium oxides, antioxidants like Vitamin E, Erganox 1010, colorants, dyes, UV stabilizers like Tinuvin 292, Tinuven 1130, Tinuven 171, etc. For this work, Vitamin E was obtained from Sigma/Aldrich, and the Irganox 1010 was from BASF.

As used herein, non-woven materials are a category of materials made primarily of textile fibers that are not made by conventional weaving or knitting, but rather the fibers are bonded together by bonding, fusing, or other chemical, thermal, mechanical, or solvent treatment. For example, non-woven materials suitable for use in the present invention can be chemically formed from a polyolefin (e.g. polyethylene and polypropylene), polyester, polyurethane, polyamide, polyaramide or glass. In some embodiments, the non-woven material may be a spun bonded non-woven (i.e., a non-woven fabric formed by filaments that have been spun, drawn, cut then spread on a conveyor belt). In other embodiments, the non-woven material may be a spun bonded polypropylene/polyethylene, for example Tytar® or Remy®. Alternatively, the non-woven material may be spun-laced (non-woven fabric made by entangling of fibers in a repeating pattern to form a strong binders free fabric), carded (non-woven fabric produced by a process similar to carding wool in textile industry), "hook" or "loop" fabrics used in hook and loop fasteners, radiation-grafted, or other known variations. In some embodiments, the non-woven material may be a carded polypropylene/rayon. In other embodiments, the non-woven material may be radiation grafted rayon fibers or a composite polyacrylate laminate consisting of Superabsorbent polymers (SAP) and cellulose. In some embodiments, the non-woven material may be a meltblown non-woven.

Further examples of suitable non-woven material include felt and synthetic fibers such as polyester; polyolefins (e.g., polyethylene, polypropylene and the like); polyurethane; polyamide (e.g., NYLON® fiber); polyaramide (e.g., KEVLAR(R) fiber); and glass (e.g., FIBERGLAS™ fiber). In some embodiments, the non-woven material may be a non-woven polyolefin fabric, such as DELNET® fabric from DelStar Technologies, Inc. (Middletown, DE).

The term "oral care substance" includes curative, prophylactic and cosmetic active substances or compositions thereof. Suitable oral care substances include any substance that is generally considered to be safe for use in the oral cavity and that provides or prevents a change to the overall health of the oral cavity. Examples of oral care substances may include, but are not limited to one or more of desensitizing agents, whitening substances, stain bleaching agents, stain removal agents, plaque removal agents, tartar removal agents, calcification removal agents, cavity prevention and treatment agents, remineralizing agents, caries control agents, antimicrobial agents, bactericides/disinfectants, anti-fungal, antibiotics,

analgesic agents, anti-inflammatory agents, nutrients, enzymes, anesthetics and antioxidants. The following is a non all-inclusive list of oral care substances that may be used in the present invention.

Suitable whitening substances include, but not limited to, peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combinations thereof. Suitable peroxides include: hydrogen peroxide, calcium peroxide, carbamide peroxide, and mixtures thereof. In some embodiments, the oral care substance may be hydrogen peroxide. Suitable metal chlorites include calcium chlorite, barium chlorite, magnesium chlorite, lithium chlorite, sodium chlorite, potassium chlorite, hypochlorite and chlorine dioxide. In some embodiments, the oral care substance may be sodium chlorite.

Suitable anti-tartar/anti-calculus agents include, but not limited to, phosphates such as pyrophosphates (e.g. dialkali metal pyrophosphate salts, and tetra-alkali metal pyrophosphate salt), polyphosphates, polyphosphonates (e.g., ethane- 1-hydroxy-1,1-diphosphonate, 1-azacycloheptane-1,1-diphosphonate, and linear alkyl diphosphonates), and salts thereof; synthetic anionic polymers; linear carboxylic acids; and sodium zinc citrate; and mixtures thereof. In some embodiments, the oral care substance may be the hydrated or unhydrated forms of disodium dihydrogen pyrophosphate ($\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$), tetrasodium pyrophosphate ($\text{Na}_4\text{P}_2\text{O}_7$), or tetrapotassium pyrophosphate ($\text{K}_4\text{P}_2\text{O}_7$). Anticalculus phosphates include potassium and sodium pyrophosphates; sodium tripolyphosphate; diphosphonates (e.g. ethane- 1-hydroxy-1,1-diphosphonate, 1-azacycloheptane- 1,1-diphosphonate, and linear alkyl diphosphonates); linear carboxylic acids and sodium and zinc citrate. Suitable synthetic anionic polymers include polyacrylates and copolymers of maleic anhydride or acid and methyl vinyl ether, polyamino propane sulfonic acid (AMPS), zinc citrate trihydrate, polyphosphates (e.g. tripolyphosphate; hexametaphosphate), diphosphonates (e.g. EHDP, AHP), polypeptides (such as polyaspartic and polyglutamic acids), and mixtures thereof.

Suitable caries and cavity control agents include fluoride ions (e.g. sodium fluoride, potassium fluoride, stannous fluoride, and ammonium fluoride).

Suitable antimicrobial agents include, but not limited to, 5-chloro- 2-(2,4-dichlorophenoxy)-phenol (i.e. triclosan), chlorhexidine, alexidine, hexetidine, sanguinarine, benzalkonium chloride, salicylamide, domiphen bromide, cetylpyridium chloride (CPC), tetradecylpyridinium chloride (TPC); N-tetradecyl-4-ethyl 1pyridinium chloride (TDEPC); octenidine; delmopinol, octapinol, and other piperidino derivatives, niacin preparations; zinc/stannous ion agents.

Suitable antibiotics include, but not limited to, penicillin, meticillin, oxacillin, cefalotin, cefaloridin, erythromycin, lincomycin, tetracycline, chlortetracycline, oxytetracycline, metacycline, chloramphenicol, kanamycin, streptomycin, gentamicin, bacitracin; and cycloserine; and analogs and salts of the above antibiotics.

Suitable anti-inflammatory agents include, but not limited to, non-steroidal anti-inflammatory/analgesic agents, such as acetaminophen, methyl salicylate, monoglycol salicylate, aspirin, mefenamic acid, flufenamic acid, indomethacin, diclofenac, alclofenac, diclofenac sodium, ibuprofen, flurbiprofen, fentizac, bufexamac, piroxicam, phenylbutazone, oxyphenbutazone, clofezone, pentazocine, mepirizole, and tiaramide hydrochloride; and steroidal anti-inflammatory agents, such as hydrocortisone,

prednisolone, dexamethasone, triamcinolone acetonide, fluocinolone acetonide, hydrocortisone acetate, prednisolone acetate, methylprednisolone, dexamethasone acetate, betamethasone, betamethasone valerate, flumetasone, flourometholone, budesonide, and beclomethasone dipropionate.

Suitable anesthetics include, but not limited to, dibucaine hydrochloride, dibucaine, lidocaine hydrochloride, lidocaine, benzocaine, p-buthylaminobenzoic acid 2-(diethylamino)ethyl ester hydrochloride, procaine hydrochloride, tetracaine hydrochloride; chloroprocaine hydrochloride, oxyprocaine hydrochloride, mepivacaine, cocaine hydrochloride; and piperocaine hydrochloride.

Suitable bactericides/disinfectants include, but not limited to, thimerosal, phenol, thymol, benzalkonium chloride, benzethonium chloride, chlorhexidine, providone iodide, cetylpyridinium chloride, eugenol, and trimethylammonium bromide.

Suitable antifungal drugs include, but not limited to, amphotericin, clotrimazole, econazole nitrate, fluconazole, griseofulvin, itraconazole, ketoconazole, miconazole, nystatin, terbinafine hydrochloride, undecenoic acid, and zinc undecenoate.

Suitable desensitizing agents include, but not limited to, potassium nitrate and strontium chloride.

Suitable enzymes include, but not limited to, proteases that break down salivary proteins which are absorbed onto the tooth surface and form the pellicle, or first layer of plaque; lipases that destroy bacteria by lysing proteins and lipids which form the structural component of bacterial cell walls and membranes; dextranases, glucanohydrolases, endoglycosidases, and mucinases that break down the bacterial organic skeletal structure that forms a matrix for bacterial adhesion; and amylases that prevent the development of plaque and calculus by breaking-up the calcium binding carbohydrate-protein complex. In some embodiments, the oral care substance may be any of the commercially available proteases, dextranases, glucanohydrolases, endoglycosidases, amylases, mutanases, lipases, mucinases, and compatible mixtures thereof.

Suitable nutrients include, but not limited to, Vitamins (e.g., Vitamins C and D, thiamine, riboflavin, calcium pantothenate, niacin, folic acid, nicotinamide, pyridoxine, cyanocobalamin, para-aminobenzoic acid, and bioflavonoids), oral nutritional supplements, enteral nutritional supplements, and minerals (e.g., calcium, phosphorus, fluoride, zinc, manganese, and potassium), and mixtures thereof.

Suitable antioxidants include, but are not limited to Vitamin E, ascorbic acid, Uric acid, carotenoids, Vitamin A, flavonoids and polyphenols, herbal antioxidants, melatonin, aminoindoles, lipoic acids and mixtures thereof.

In some embodiments, the oral care substance may be Histamine-2(H-2) receptor antagonist (H-2 antagonists) (i.e. compounds that block H-2 receptors, but do not affect histamine-1(H-1) receptors.).

The fill-level of oral care substance of preformed dental devices may be from about 0.01% to about 50% of the preformed device by volume. In some embodiments, the fill-level of oral care substance may be from about 0.1% to about 20% of the preformed device by volume.

The oral care substance may be in the form of a solid (e.g. particles), liquid (e.g. viscous liquid, solution), paste, gel, or any other suitable form. The gel may be an aqueous or non-aqueous (e.g. based on glycerol) gel, and may also contain a gelling or thickening agent.

In some embodiments, the oral care substance may be in the form of an aqueous gel, the water present in the gel compositions should be deionised and free of organic impurities. A pH adjusting agent may be added to optimize the storage stability of the gel and to make the substance suitable for the oral tissues. The pH adjusting agents, or buffers, can be any suitable material to adjust the pH of the oral care substance. Suitable pH adjusting materials include sodium bicarbonate, sodium phosphate, sodium hydroxide, ammonium hydroxide, sodium stannate, triethanolamine, citric acid, hydrochloric acid, sodium citrate, and combinations thereof.

As shown in FIG. 4, in some embodiments, the dental device 70 may be preloaded with the oral care substance 80. The oral care substance may be deposited upon a surface of the dental device, For example a gel may be deposited directly as a layer on a surface of a dental device as described above. Alternatively a gel may be absorbed into the above-mentioned non-woven material, or impregnated into the bulk of a non-woven material.

Methods of depositing substances upon the surfaces of dental devices as described above include, but are not limited to printing (e.g. silk screen printing), passing between impregnated rollers, dosing, a pump and nozzle, spraying, dipping, pouring and etc. Methods of impregnating substances into the bulk of a non-woven material include, but are not limited to admixing the substance into the non-woven material, or exposure of the non-woven material to the substance under conditions which cause the substance to be impregnated into the non-woven material. Alternatively, example dental device may comprise a foam material, particularly an open-cell foam material, and the substance may be impregnated into the dental device by introducing the substance into the cells of the foam. The substance may subsequently be released from the dental device by mechanic force, the action of moisture in the oral cavity by dissolving the substance, or the effect of chemicals, enzymes (e.g. saliva amylases) and etc, present in the oral cavity.

In some embodiments, the dental device may have a pattern (e.g. an array of dimples, ridges, diamonds, or scales) formed by embossing or a similar method on a surface of the device. It is found that the pattern helps to retain the oral care substance on the dental device.

In some embodiments, there are provided kits comprising a plurality of dental devices including any one of those described above. The dental devices may be stacked, packaged, or put into a package. For certain embodiments, the plurality of dental devices may include a plurality of sizes.

A typical process for making the above-mentioned device of the invention may involve the following steps. The malleable material sheets may be sized by compressing them, e.g. between rollers, to compress them to a suitable thickness, e.g. as mentioned above. A non-woven material may then be attached to the layer of malleable material by known methods, for example by bringing the non-woven material into contact with a surface of the layer of malleable material and applying pressure. The layer of malleable material and the non-woven material may be rolled together between rollers. The sheet of laminated material may then be cut or punched to a shape (e.g. flat sheet, dual arch flat sheet), for example using a die cutter. The oral care substance may then be applied to the layer of non-woven material, using a conventional method such as applying by means of a roller, a delivery pump, or a

nozzle. The dental device may be perforated so that a user can tear off the unneeded portion of the device to achieve the desired size.

In some embodiments, the dental device may be used for delivering an oral care substance to a patient's oral hard or soft tissues.

5 In one embodiment, a method for applying an oral care substance to a patient's hard and soft oral tissues is described. The method generally comprises providing a dental device, the dental device comprising a layer of an orally acceptable malleable material, the malleable material layer sized to cover a dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable material layer. The method further comprises placing the dental device in contact with the teeth of a dental arch and/or gingiva. When using the device, the malleability of the malleable material causes the device to become conformed to the profile of the teeth, and to fit into the gaps between the teeth. If the device is greater than the length of the teeth it may be modified to a desired size. For example, the device may be folded over the distant ends of the teeth to contact the rear surfaces of the teeth and be pressed against the rear surface, thereby becoming shaped to the rear surfaces of the teeth. The oral care substance may be applied to the dental device after the device is removed from oral cavity. The device may then be applied manually to a patient's tooth and/or gingiva surface(s), for example by applying finger pressure or using an applicator device to position the device on or adjacent to the tooth surface. The device is applied by the user to a patient's teeth and/or gingiva, with the length dimension of the device aligned with the line of the patient's teeth, the substance-bearing surface in contact with the front surface of the teeth and/or gingiva, and the device is pressed against the front surface of the teeth and/or gingiva. The device is left in contact with the patient's teeth and/or gingiva for a sufficient length of time for the oral care substance to take effect. The period of use will depend upon the particular patient, preference, the state of the patient's teeth, the healthcare effect desired, e.g. degree of whitening required etc. This period may for example be as short as 10 minutes, or may be longer for example 2 hours, and the device may be applied for plural sessions each day, e.g. two 30 minute sessions per day.

If the device is preformed or the oral care substance is preloaded onto the device, variants of the above-described methods may be used, as described below.

In some embodiments, the dental device may be partially adapted to a generic arch shape. The partially adapted dental device is then conformed to the profile of the teeth and customized to fit a dental arch and/or gingiva.

In some embodiments, the dental device may be preformed to fit the overall shape of a dental arch and/or gingiva. Thus, the oral care substance may be directly applied to the dental device without the step of conforming the dental device to fit to the dental arch and/or gingiva.

In other embodiments, the dental device may be preloaded with the oral care substance. The dental device may be placed in contact with the teeth of a dental arch and/or gingiva without the step of applying the oral care substance to the dental device.

In some embodiments, a dual arch flat sheet dental device may be provided. The dental device is folded so that open side of the dual arch may be exposed. The folded dental device is placed in contact

with the teeth of both upper and lower dental arch and/or gingiva. The device is then conformed to the profile of the teeth, and to fit into the gaps between the teeth.

Alternatively, the dual arch dental device may be preformed to a generic arch shape.

5 **EXAMPLES**

Preparation of Conformable Oral Delivery Tray

A malleable oral delivery tray was prepared as described as follows.

10 **Example 1**

Sheets of malleable dental wax (Coltene Whaledent, Cuyahoga Falls, OH) were pressed out in a bench top hydraulic press (Carver Inc., Wabash, IN) under approximately 1 metric ton or 2000 psi of pressure at room temperature. Samples were pressed between 0.05 mm sheets of film to a thickness of ~ 2 mm using metallic spacers to control the as-formed thickness. The wax sheets obtained by this process were
15 immediately transferred to a 37C incubator and kept warm until use. These warm wax sheets were then laminated to top layer (PP/Rayon, Ahlstrom, Windsor Locks, CT) and bottom layer (85 PP/15 PE, 3M Company, St. Paul, MN) by hand pressure until the wax was at least partially invested into the aforementioned layers. This layered configuration was then flattened against a stainless steel plate using a hand roller type implement. The shape of the conformable oral delivery tray, either as a single or dual-
20 arch configuration, was then punched out of the layered composition with a die resulting in a planar piece ready for configuration (or not) around the dentition. As shown in FIG. 3A, the formed trays 70 were molded around a full arch typodont model 60 (Columbia Dentoform, Long Island City, NY) and removed to form the free-standing oral delivery tray 70 as shown in FIG. 3B.

25 **Example 2**

Sheets of malleable dental wax were pressed out as described in Example 1 to a thickness of ~ 2 mm between sheets of film. The resulting wax sheets were warmed and laminated to top and bottom layers as described in Example 1. The resulting layered configuration was flattened as described in Example 1. The shape of the conformable oral delivery tray was punched out and molded as described in Example 1.
30 In this case, the formed free-standing oral delivery tray is preloaded with an experimental 2% sodium fluoride aqueous gel (3M Company, St. Paul, MN).

The complete disclosures of all patents, patent documents, and publications cited herein are expressly incorporated by reference in their entirety as if each were individually incorporated. Various
35 modifications and alterations to this invention will become apparent to those skilled in the art without departing from the scope and spirit of this invention. It should be understood that this invention is not intended to be unduly limited by the illustrative embodiments and examples set forth herein and that such

examples and embodiments are presented by way of example only with the scope of the invention intended to be limited only by the claims set forth herein as follows and equivalents thereof.

What Is Claimed Is:

1. A dental device, comprising: a layer of a malleable material, the malleable material layer shaped to envelop a dental arch and/or gingiva; and a non-woven material in contact with at least a portion of one side of the malleable material layer.

2. The dental device of claim 1, wherein the dental device is generally planar.

3. The dental device of claim 2, wherein the dental device has a first arch extending in a curved configuration extending from a first end to a second end, and an opposing second arch extending in a curved configuration extending from a first end opposite the first end of the first arch to a second end opposite the second end of the first arch.

4. The dental device of claim 1, wherein the dental device is preformed to fit the overall shape of a dental arch and/or gingiva.

5. The dental device of claim 1, wherein the dental device is partially adapted to a generic arch shape, fitting over a plurality of differently-sized dental arches.

6. The dental device of claims 1-5, wherein the dental device is capable of being modified.

7. The dental device of claim 6, wherein the dental device is capable of being modified by trimming, cutting, tearing, bending, or folding.

8. The dental device of claim 1, wherein the layer of malleable material is about 1mm to 5mm in thickness.

9. The dental device of claim 8, wherein the layer of malleable material is about 2mm in thickness.

10. The dental device of claim 1, wherein the malleable material comprises a wax or a polymeric compound, a rubber, or a mixture thereof.

11. The dental device of claim 10, wherein the malleable material comprises a polymeric compound.

12. The dental device of claim 11, wherein the polymeric compound is a polysaccharide, water-soluble synthetic polymer, polypeptide, natural gum, or a mixture thereof.

13. The dental device of claim 10, wherein the malleable material comprises a wax.

14. The dental device of claim 13, wherein the wax is a paraffin wax, microcrystalline wax, or a mixture thereof.

15. The dental device of claim 10, wherein the malleable material comprises a rubber.

16. The dental device of claim 15, wherein the rubber is an oil-filled thermoplastic elastomeric rubber.

17. The dental device of claim 1, wherein one or more non-woven material is in contact with at least a portion of opposing sides of the malleable material layer.

18. The dental device of any of the previous claims, having a tab extending from the dental device.

19. The dental device of any of the previous claims, wherein the dental device is preloaded with an oral care substance.

20. The dental device of claim 19, wherein the oral care substance is a desensitizing agent, whitening substance, stain bleaching agent, stain removal agent, plaque removal agent, tartar removal agent, calcification removal agent, cavity prevention and treatment agent, remineralizing agent, caries control agent, antimicrobial agent, anti-fungal, antibiotic, analgesic agent, anti-inflammatory agent, nutrient, enzyme, antioxidant, or a mixture thereof.

21. The dental device of claim 19, wherein the oral care substance is in the form of a gel, liquid, or solid.

22. The dental device of any of the previous claims, having a retentive pattern on a surface of the device.

23. A kit comprising a plurality of dental devices of any one of the previous claims.

24. A use of the dental device of claims 1-22 for delivering an oral care substance to a patient's oral hard or soft tissues.

25. A method for applying an oral care substance to a patient's hard and soft oral tissues, comprising:
providing a dental device, the dental device comprising,
a layer of an orally acceptable malleable material, the malleable material layer sized to cover a dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable material layer;
placing the dental device in contact with the dental arch and/or gingiva;

conforming the dental device to fit to the dental arch and/or gingiva;
removing the dental device from the dental arch and/or gingiva;
applying the oral care substance to the dental device; and
treating the dental arch and/or gingiva with the oral care substance.

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26. A method for applying an oral care substance to a patient's hard and soft oral tissues, comprising:
providing a dental device, the dental device comprising,
a layer of an orally acceptable malleable material, the malleable material layer sized to cover a
dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable
material layer, wherein the dental device is preformed to fit the overall shape of the dental arch and/or
gingiva;
applying the oral care substance to the dental device; and
treating the dental arch and/or gingiva with the oral care substance.

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27. A method for applying an oral care substance to a patient's hard and soft oral tissues, comprising:
providing a dental device, the dental device comprising,
a layer of an orally acceptable malleable material, the malleable material layer sized to cover a
dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable
material layer, wherein the dental device is preloaded with the oral care substance;
placing the dental device in contact with the dental arch and/or gingiva;
conforming the dental device to fit to the dental arch and/or gingiva; and
treating the dental arch and/or gingiva with the preloaded oral care substance.

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28. A method for applying an oral care substance to a patient's hard and soft oral tissues, comprising:
providing a dental device, the dental device comprising,
a layer of an orally acceptable malleable material, the malleable material layer sized to cover a
dental arch and/or gingiva; and a non-woven material in contact with at least one side of the malleable
material layer, wherein the dental device is preformed to fit the overall shape of the dental arch and/or
gingiva and wherein the dental device is preloaded with the oral care substance; and
treating the dental arch and/or gingiva with the preloaded oral care substance.

30

29. The method of claims 25-28, wherein the oral care substance is a desensitizing agent, whitening
substance, stain bleaching agent, stain removal agent, plaque removal agent, tartar removal agent,
calcification removal agent, cavity prevention and treatment agent, remineralizing agent, caries control
agent, antimicrobial agent, anti-fungal, antibiotic, analgesic agent, anti-inflammatory agent, nutrient,
enzyme, antioxidant, or a mixture thereof.

35

30. The method of claims 25-28, further comprising modifying the dental tray to a desired size.

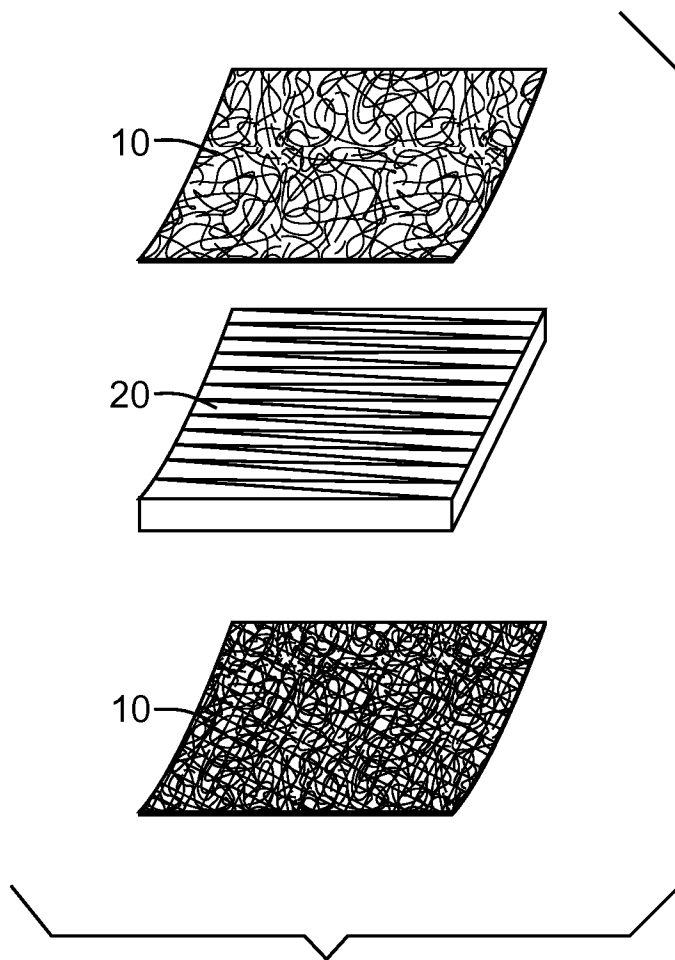


FIG. 1

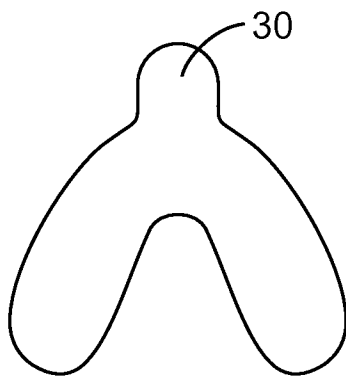


FIG. 2A

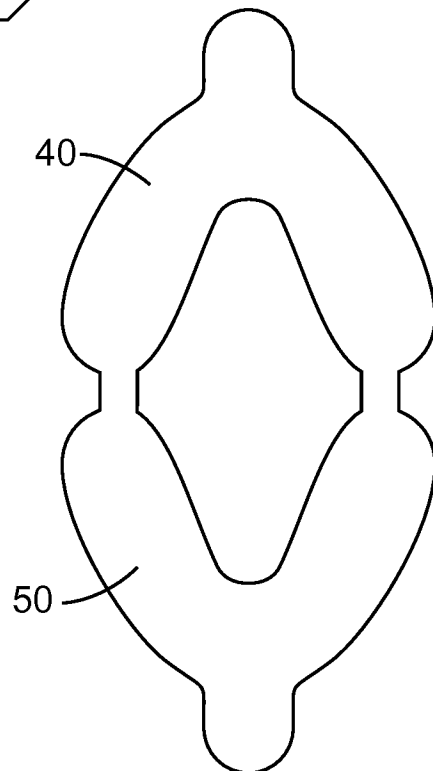


FIG. 2B

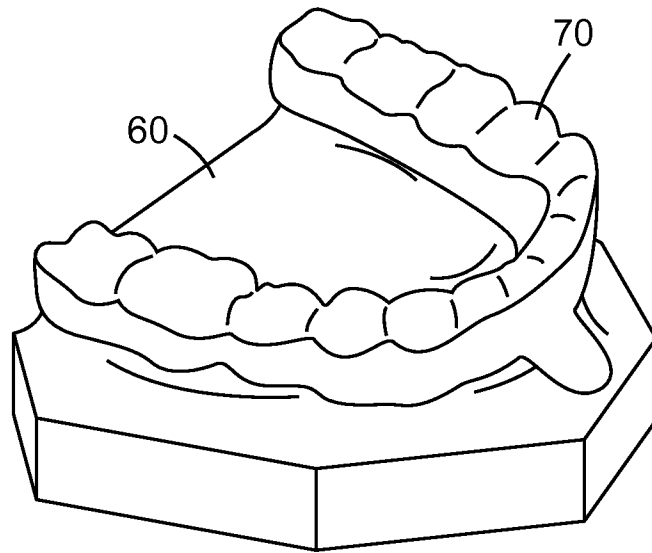


FIG. 3A

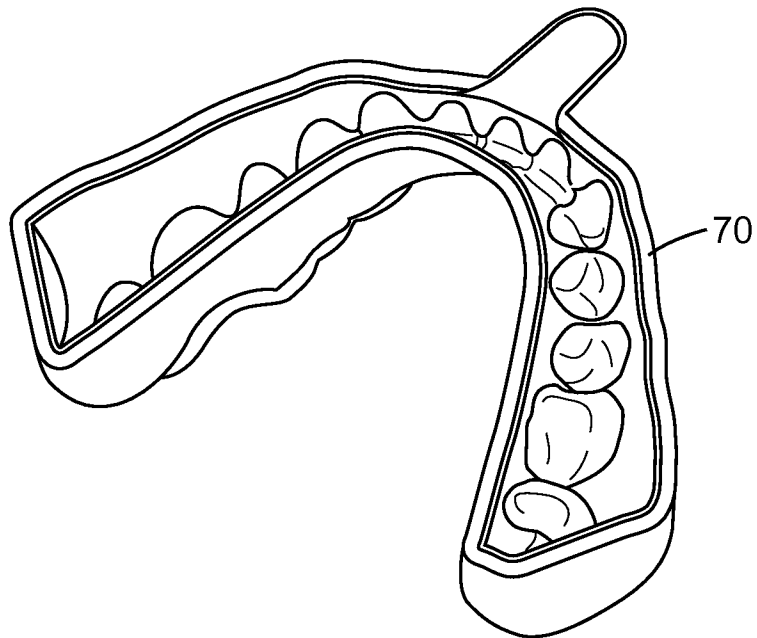


FIG. 3B

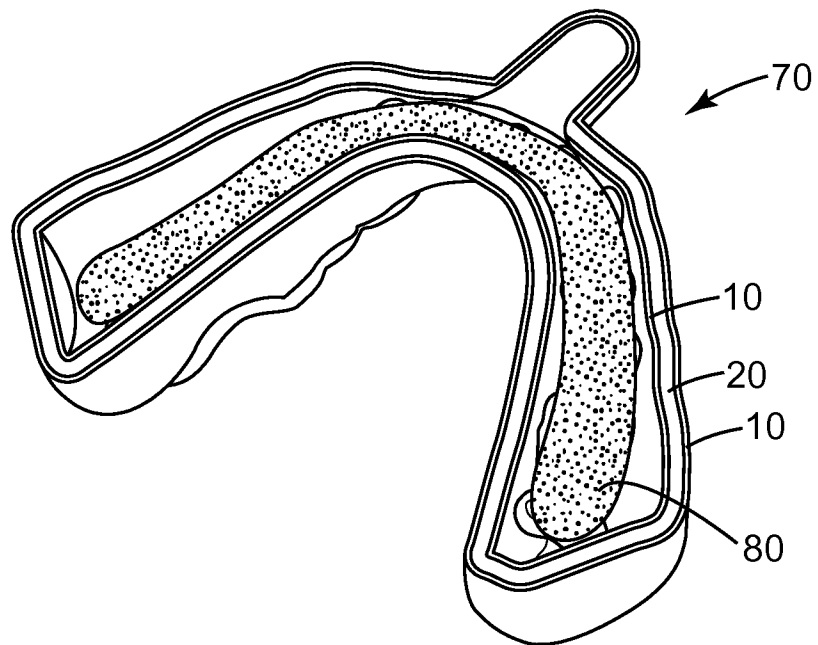


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/039693

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61C19/06
 ADD.

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)
 A61C

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)

EPO-Internal, COMPENDEX, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/241620 A1 (ALLRED PETER M [US] ET AL) 2 December 2004 (2004-12-02)	1,2, 4-12,15, 17, 19-21,23
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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 application or patent but 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

23 August 2013

Date of mailing of the international search report

03/09/2013

Name and mailing address of the ISA/

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Kunz, Lukas

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/039693

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 6 274 122 B1 (MCLAUGHLIN GERALD [US]) 14 August 2001 (2001-08-14) page 2, line 30 - page 12, line 24; figures 1-5	1,4-12, 17,19-22 13,14 2,3,15, 16,18,23
X A	----- US 4 173 219 A (LENTINE FRANK N [US]) 6 November 1979 (1979-11-06) column 1, line 61 - column 4, line 24; figures 1-5	1-9,18, 20-22 10-17, 19,23
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/039693

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 24-30
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 24 to 30 concern methods for applying an oral care substance to a patient's hard or soft oral tissues. This is a treatment of the human body by therapy, for which no search and examination has to be carried out (Articles 17 (2) a) i) and 34 (4) a) i) PCT and Rules 39.1 iv) and 67.1 iv) PCT).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/039693

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/039693

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