US 20110171606A1

(19) **United States**

(12) **Patent Application Publication**

Lewis et al.

(10) **Pub. No.: US 2011/0171606 A1**

(43) **Pub. Date: Jul. 14, 2011**

(54) **DENTAL TREATMENT DEVICES**

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(21) Appl. No.: **13/074,485**

(22) Filed: **Mar. 29, 2011**

Related U.S. Application Data

(62) Division of application No. 12/183,303, filed on Jul. 31, 2008.

(60) Provisional application No. 61/190,054, filed on Aug. 31, 2007.

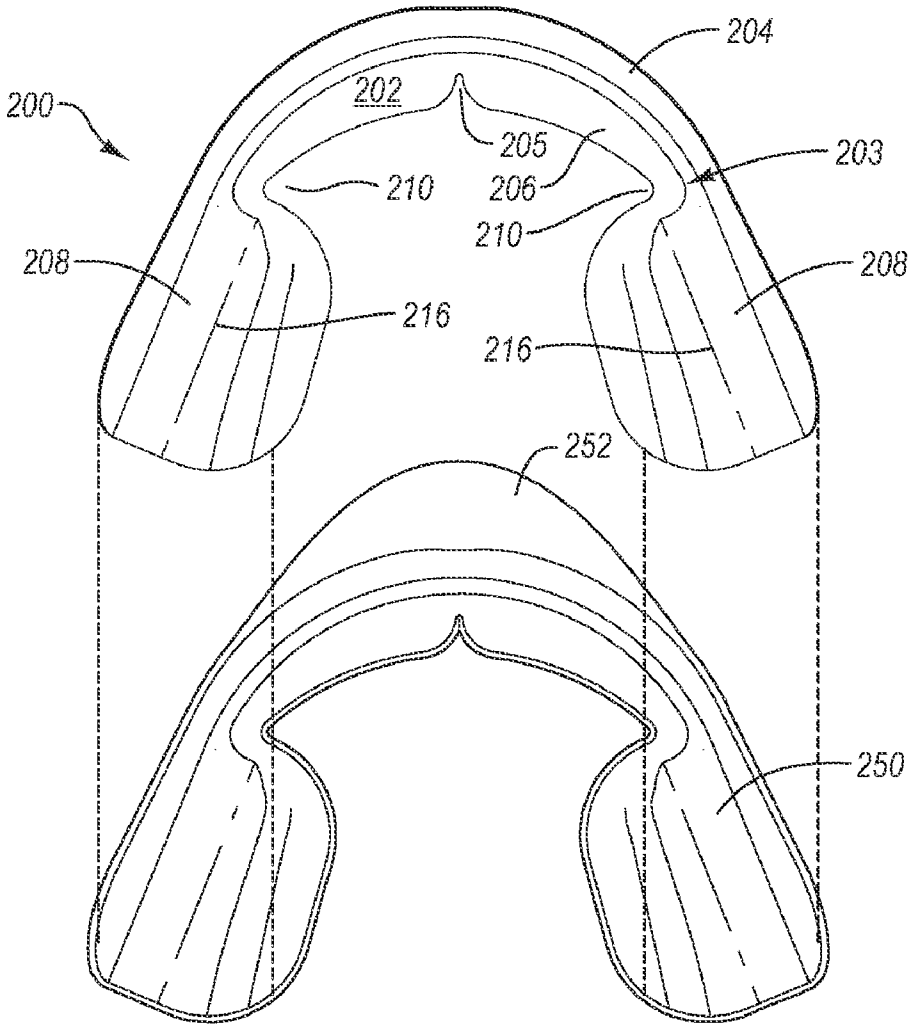
Publication Classification

(51) **Int. Cl.**
A61C 19/06 (2006.01)

(52) **U.S. Cl.** **433/217.1**

(57) **ABSTRACT**

Dental treatment trays or strips include a moisture-resistant barrier layer that is flexible so as to conform to a plurality of differently-sized and shaped dental arches during use. The moisture-resistant barrier layer comprised of wax, paraffin wax and/or polyolefin. The dental treatment device also includes a substantially solid dental treatment composition adapted so as to be initially substantially dry to the touch and so as to become sticky and adhesive to dental tissue when moistened. The substantially solid dental treatment composition includes at least one adhesive agent and at least one active agent, such as a dental bleaching agent.



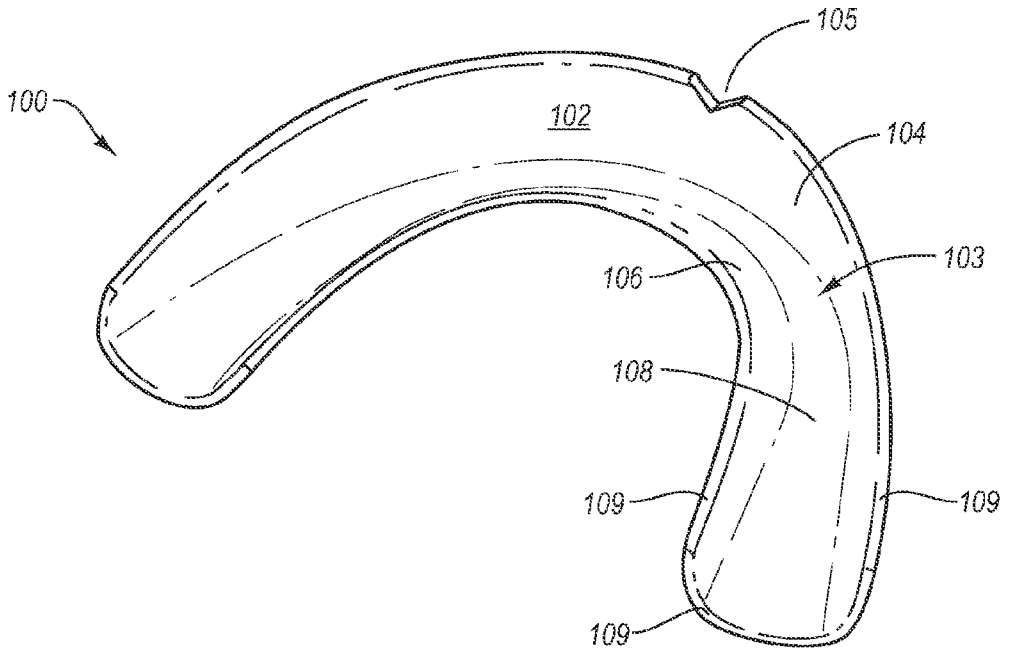


FIG. 1

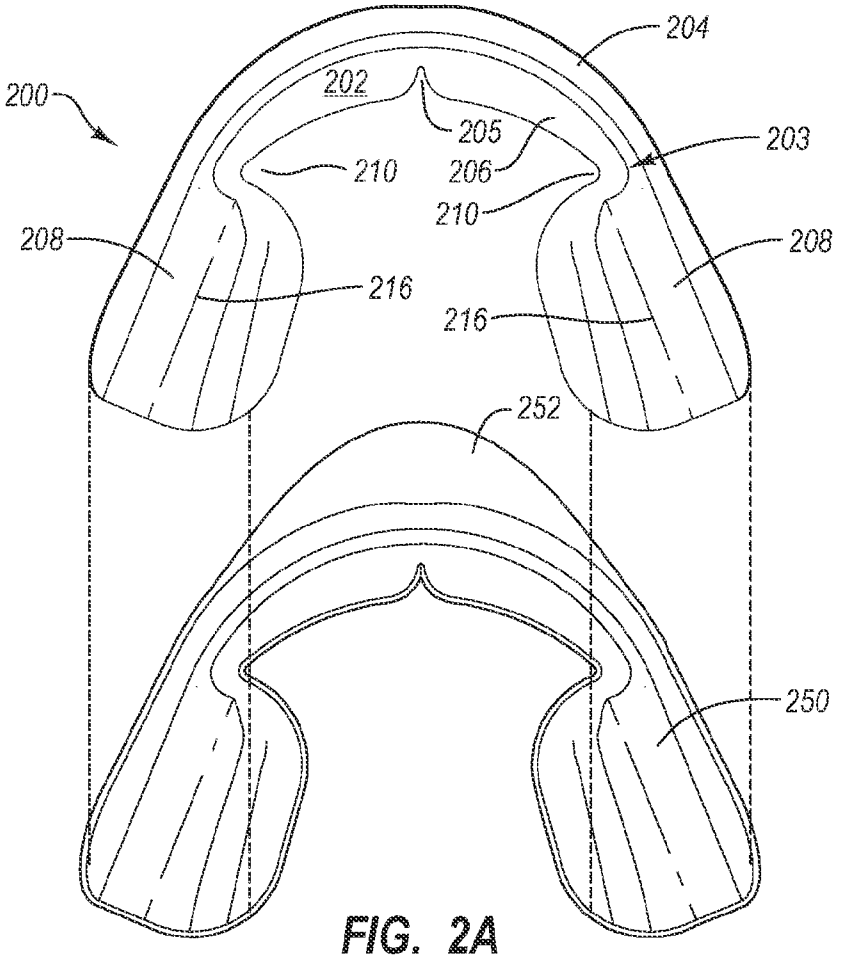

204
202
200
205
203
210
206
210
208
208
216
216
252
250

FIG. 2A

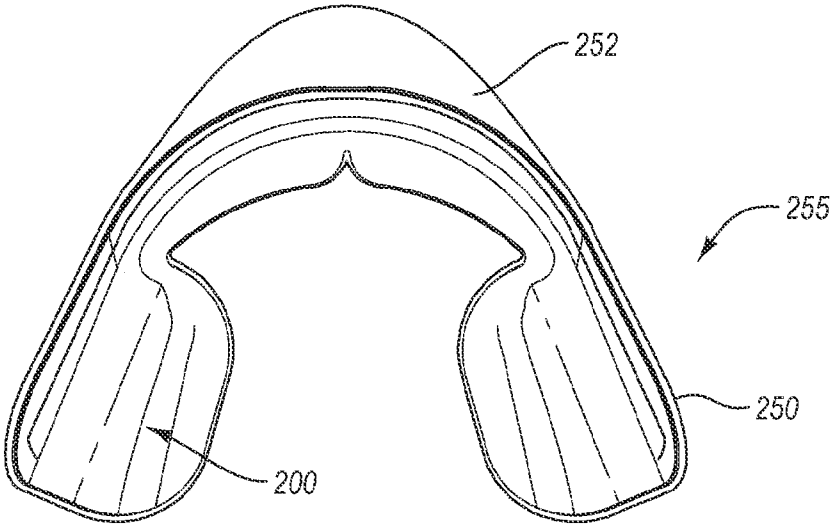

252
255
250
200

FIG. 2B

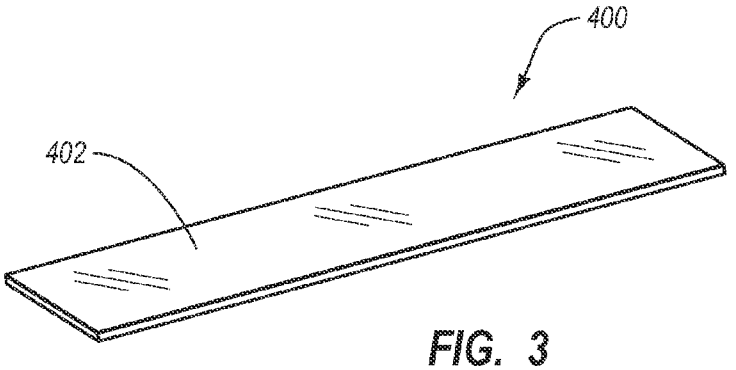


FIG. 3

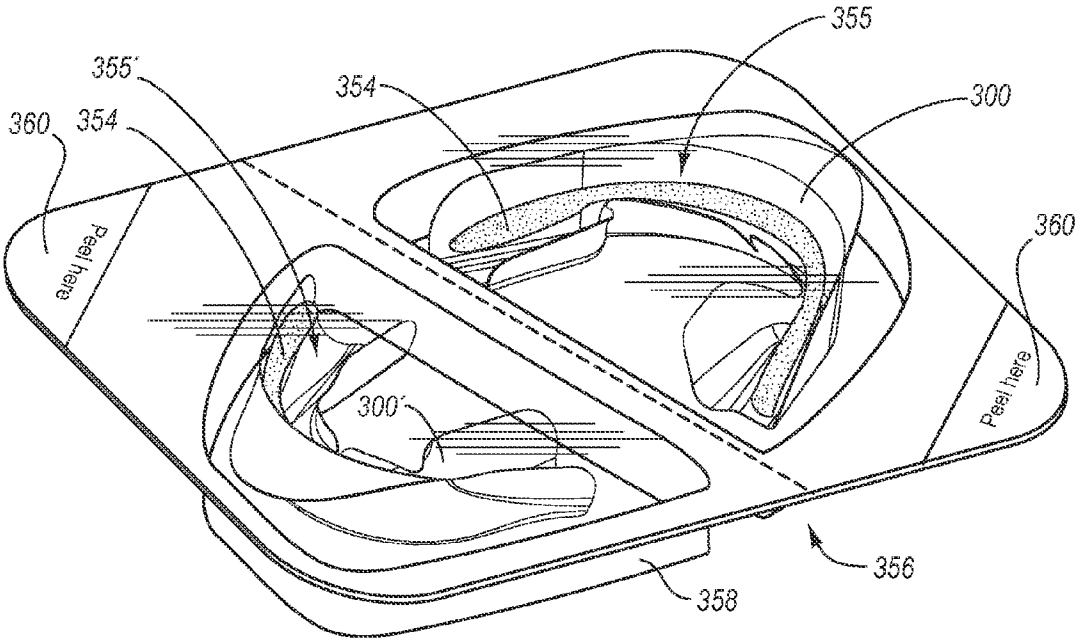


FIG. 4

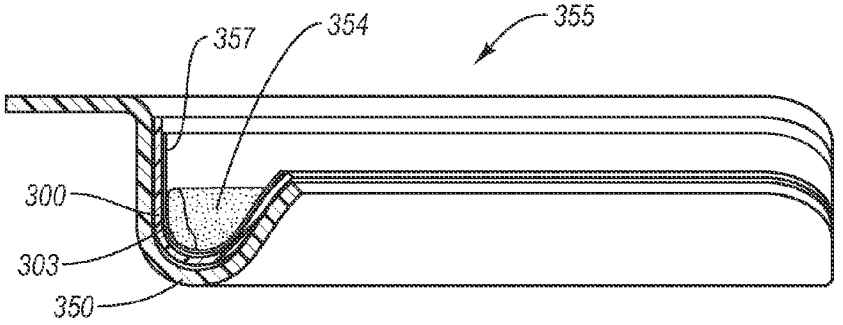


FIG. 5

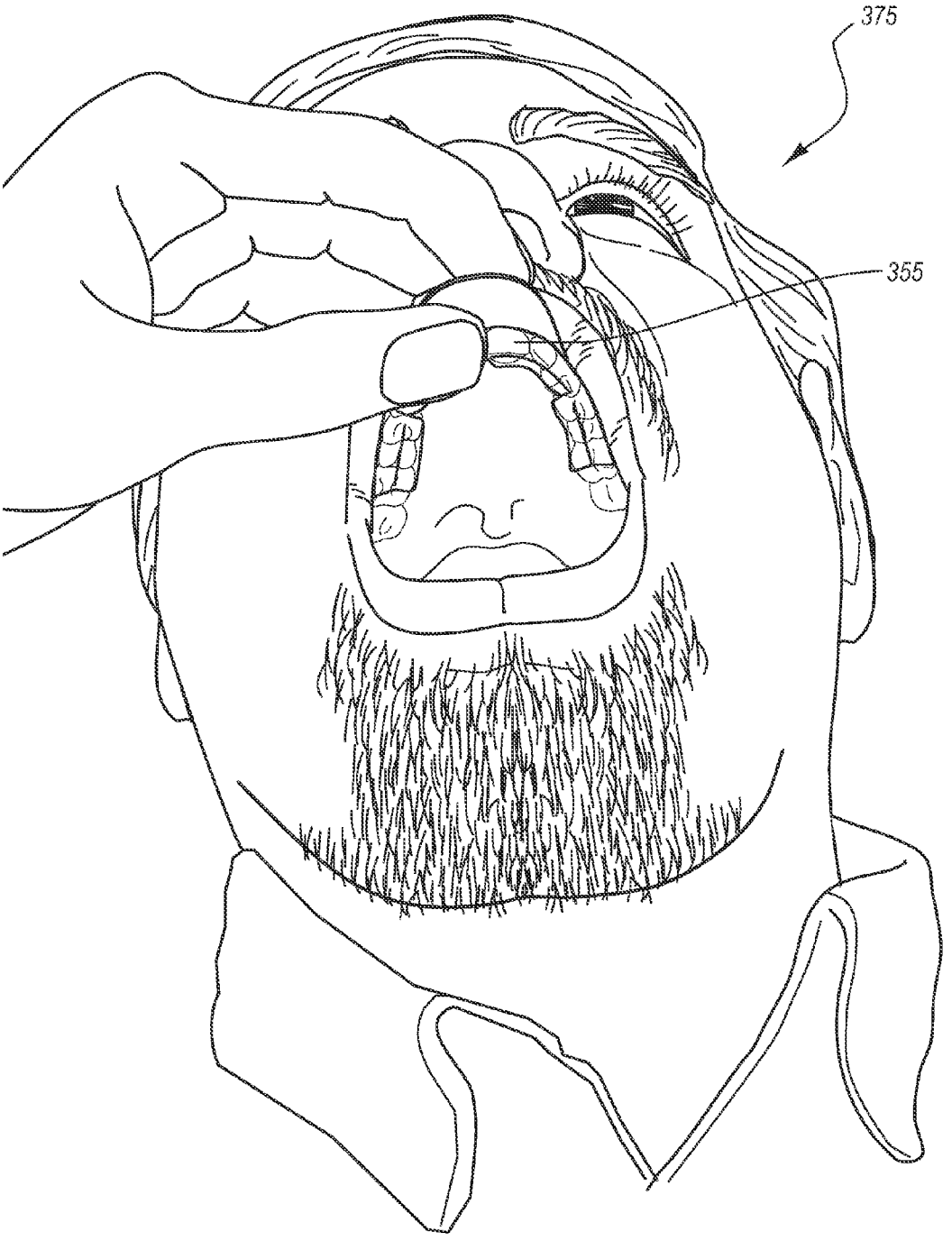


FIG. 6A

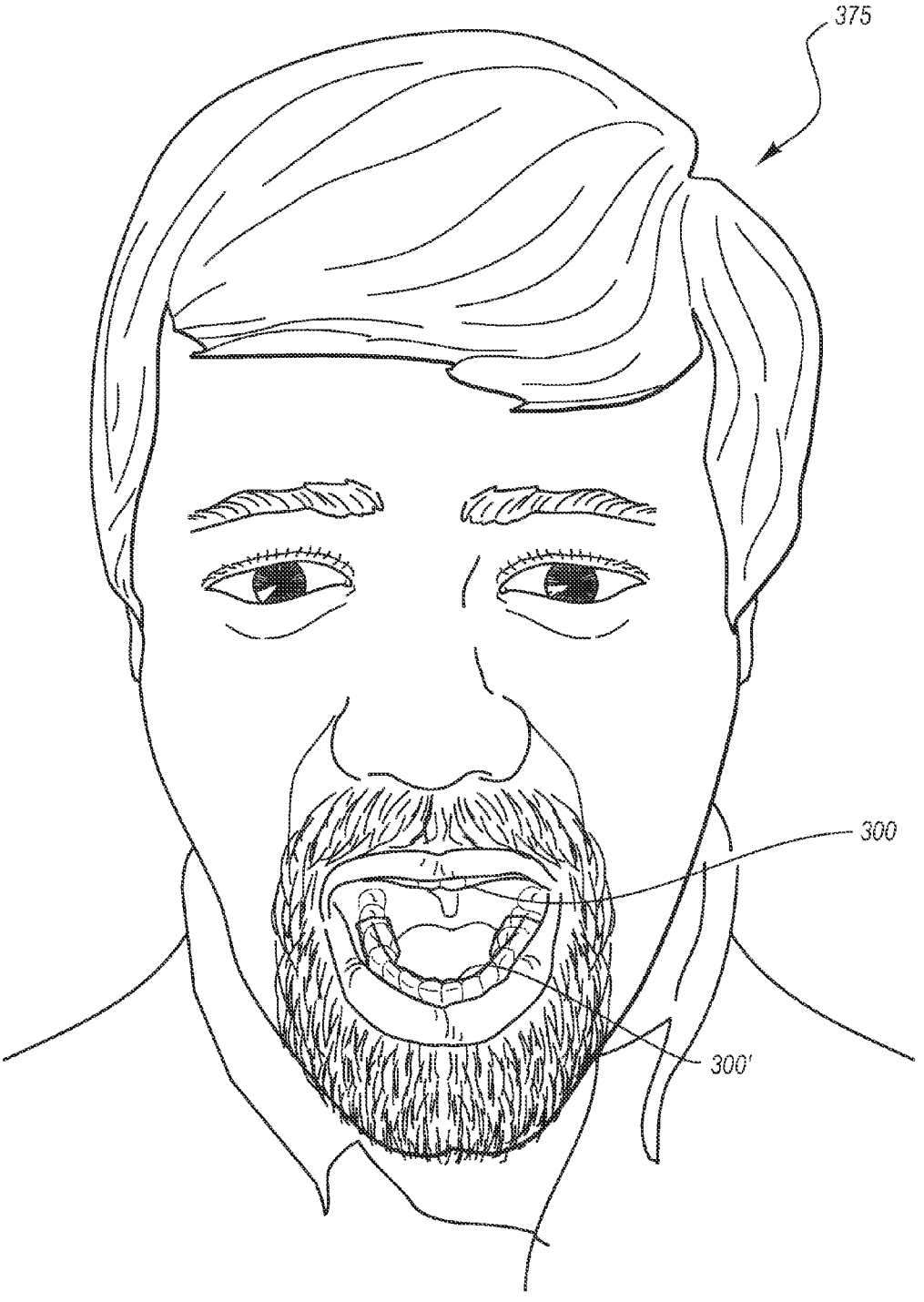


FIG. 6B

DENTAL TREATMENT DEVICES

RELATED APPLICATIONS

[0001] This application is a divisional of U.S. patent application Ser. No. 12/183,303, filed Jul. 31, 2008, which claims the benefit of U.S. Provisional Application No. 61/190,054, filed Aug. 31, 2007. The disclosures of the foregoing applications are incorporated herein in their entirety.

BACKGROUND OF THE INVENTION

[0002] 1. The Field of the Invention

[0003] The present invention is in the field of shaped, flexible dental trays and strips used to deliver a dental bleaching composition to a person's teeth. More particularly, the invention relates to flexible dental trays and strips with enhanced user comfort and tooth adhesion.

[0004] 2. The Relevant Technology

[0005] Virtually all people desire white or whiter teeth. A common bleaching method involves the use of a dental tray that is custom-fitted to a person's teeth and that is therefore relatively comfortable to wear. One type of customized tray is made by vacuum forming a sheet of moisture resistant thermoplastic polymer material over a stone cast of a person's teeth, after which the custom tray may be cut out. Another is customized directly using a person's teeth as a template (e.g., "boil-and-bite" trays). Non-customized trays that approximate the shapes and sizes of a variety of users' dental arches have also been used. A dental bleaching composition is placed into the tray and the tray placed over the person's teeth for a desired period of time.

[0006] Another tooth bleaching method involves placing a flexible bleaching strip over a user's tooth surfaces. Conventional bleaching strips comprise a flexible plastic strip coated with a dental bleaching gel of moderate viscosity and relatively low stickiness on the side of the strip facing the user's teeth. To install the bleaching strip, a portion of the bleaching strip is placed over the front surfaces of the user's teeth, and the remainder is folded around the occlusal edges of the teeth and against a portion of the lingual surfaces.

[0007] Because of the generally poor adhesion of bleaching strips to the user's teeth, coupled with their generally flimsy nature, it is often difficult for the user to maintain the bleaching strip in its proper position for the recommended time. Conventional bleaching strips are prone to slip off the teeth as a result of even minimal movement of the user's mouth, jaw or tongue. It is recommended that the user not eat, drink, smoke or sleep while wearing the bleaching strip. In some cases, the bleaching strip can become so dislodged or mangled that it must be removed by the user and replaced with a fresh bleaching strip to complete the recommended bleaching time.

[0008] Ultimately, the main impediment to successful bleaching is the failure of users to complete the prescribed bleaching regimen. If the bleaching apparatus is difficult to install over a person's teeth, requires numerous repetitions to achieve observable results, and/or is uncomfortable to wear, the user may simply give up and prematurely abort the prescribed bleaching regimen. Thus, even if dental bleaching is possible using a particular bleaching apparatus or method, it is less likely to occur if the inadequacies of the bleaching apparatus or method cause a user to become discouraged before desired results are attained.

BRIEF SUMMARY OF THE PREFERRED EMBODIMENTS

[0009] The present invention generally relates to improved dental bleaching trays and strips used to deliver a dental bleaching composition to a person's teeth. The inventive dental bleaching trays and strips are formed from a moisture resistant (e.g., polymeric) material and include a bleaching agent destabilizer disposed on an inner treatment surface of the barrier layer that is oriented toward and adjacent to the person's teeth during use. The bleaching agent destabilizer may be compounded with a polymeric or other moisture resistant material from which the barrier layer is formed so that at least some destabilizer is positioned on an inner treatment surface of the tray or strip during use.

[0010] Bleaching agent destabilizers may include any known bleaching agent destabilizer that is capable of destabilizing a dental bleaching agent in order to accelerate bleaching. When peroxides are destabilized they more rapidly release oxygen radicals, which are believed to be responsible for the tooth bleaching effect. The bleaching agent destabilizer is advantageously retained on the surface and/or within the polymeric or other moisture resistant barrier layer of the tray or strip prior to use. Upon contact with a peroxide dental bleaching agent in the presence of water, the destabilizer is able to activate or destabilize the bleaching agent, resulting in the formation of free radicals from the peroxide for increased bleaching effect.

[0011] One class of bleaching agent destabilizers includes transition and/or alkaline earth metals or their ions. Non-limiting examples of suitable metals and metal ions include magnesium, iron, titanium, cobalt, nickel, copper, platinum, tin, zinc, manganese, chromium, aluminum, silver, and combinations thereof. Magnesium and/or iron ions are particularly preferred. Another class of bleaching agent destabilizer includes enzymes, particularly organo-metallic enzyme containing transition metals, such as iron. Examples of organo-metallic enzymes include "peroxidase" and "catalase".

[0012] One embodiment provides a tray or strip in which the bleaching composition is prefilled within the tray or pre-applied to the strip. In one manner, this is made possible by providing the moisture-resistant barrier layer including the bleaching agent destabilizer with a protective rupturable membrane disposed between the barrier layer and the dental bleaching composition so as to prevent premature contact between the dental bleaching agent and the bleaching agent destabilizer on or within the barrier layer. In another manner, this may be made possible by providing an anhydrous dental bleaching composition. The anhydrous dental bleaching composition may be disposed directly in contact with the barrier layer, and will not react prematurely because of the anhydrous nature of the bleaching composition. As soon as water is added to the system (e.g., when contacted with saliva by placing the pre-filled tray or strip onto the teeth), reaction between the destabilizer and bleaching composition will begin. Embodiments including an anhydrous dental bleaching composition and no ruptureable membrane should preferably be sealed within a protective package to prevent absorption of water from the surrounding air during shipment and storage.

[0013] These and other advantages and features of the present invention will become more fully apparent from the

following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by references to specific embodiments thereof, which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0015] FIG. **1** is a perspective view of an exemplary non-custom dental bleaching tray according to the invention;

[0016] FIG. **2**A is an exploded view of a dental bleaching tray having anatomical features to improve fit and an optional complementary outer support tray;

[0017] FIG. **2**B is a perspective view showing the dental bleaching tray nested within the outer support tray;

[0018] FIG. **3** is a perspective view of an exemplary dental bleaching strip according to the present invention;

[0019] FIG. **4** illustrates a pair of pre-filled tray assemblies similar to the assembly of FIG. **2**B contained within a sealed protective package having a peelable cover;

[0020] FIG. **5** is a cross-sectional view of a tray assembly including a rupturable membrane between the barrier layer and the bleaching composition;

[0021] FIG. **6**A illustrates a person placing a dental bleaching tray according to the invention over the person's upper dental arch; and

[0022] FIG. **6**B illustrates dental bleaching trays according to the invention in place over both the upper and lower dental arches.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Introduction

[0023] The present invention relates to dental bleaching trays and strips used to deliver a dental bleaching composition to a person's teeth. The trays and strips are formed from a moisture resistant material and include a bleaching agent destabilizer compounded within the moisture resistant material from which the barrier layer body is formed and/or disposed on an inner treatment surface of the barrier layer that is oriented toward and adjacent to the person's teeth during use.

II. Exemplary Chemically Activated Dental Bleaching Trays and Strips

[0024] FIG. **1** illustrates an exemplary non-custom dental bleaching tray **100** which is formed from a moisture resistant material (e.g., a two-part silicone). Dental bleaching tray **100** includes a barrier layer body **102** in the shape of a tray. The tray shaped body **102** includes a buccal-labial front side wall **104**, a lingual rear side wall **106**, and a bottom wall **108** bridging the buccal-labial wall **104** and buccal-labial wall **106**. Bottom wall **108** is adjacent to buccal-labial wall **104** such that buccal-labial wall **104** extends laterally from bottom wall **108** in a substantially vertical direction. Buccal-labial wall **104** is shown as including an optional v-shaped cut **105** formed along the top surface thereof, near the center where the incisors reside during use. Such a cut helps wall **104** to stretch and flex so as to better accommodate the incisors. Although not shown, such a similar cut or discontinuity may be formed within lingual wall **106**. Lingual wall **106** is disposed at the opposite side of bottom wall **108**, extending laterally upwardly and outwardly therefrom. The buccal-labial wall **104**, lingual wall **106**, and bottom wall **108** together form a tray shaped body **102** having an approximate U-shaped cross section and a generally horseshoe-shaped curvature.

[0025] The size, shape and curvature of the tray body **102** are advantageously selected in order for the horseshoe-shaped curvature to generally approximate the curvature of a person's dental arch. The U-shaped cross section generally corresponds to and defines an interior cavity of the tray body **102**. The depth of the interior cavity is selected in order for the buccal-labial and lingual walls **104** and **106** respectively to extend over a desired portion of a person's teeth, and optionally, over a portion of the person's gums.

[0026] Because of its non-custom nature (i.e., tray shaped body **102** is substantially devoid of structures corresponding to the size and shape of a person's unique dentition), the tray shaped barrier layer body **102** comfortably fits over a plurality of differently sized and/or shaped teeth corresponding to different people. Nevertheless, it is within the scope of the invention to provide separate dental trays that are sized and configured to correspond to either a person's upper or lower dental arch, as the lower dental arch is typically smaller than the upper arch, with lower teeth that are typically smaller than the upper teeth. It is also within the scope of the invention to provide varyingly-sized bleaching trays to account for variability among different people's dental arches and/or teeth (e.g., adults versus children, larger mouths versus average or smaller mouths, and larger teeth versus average or smaller teeth).

[0027] The tray body **102** may be injection molded, vacuum formed, cut and/or stamped from a sheet of polymeric material, although injection molding is preferred over methods that involve cutting and/or stamping because the outer edges **109** of each wall may be injection molded so as to have a smooth, rounded edge surface as opposed to the sharp, angled surfaces formed when a tray is cut or stamped from a sheet of material. Such smooth edges also contribute to the overall comfortable feel of the tray.

[0028] Tray **100** includes an inner treatment surface **103** that includes the inwardly oriented surfaces of buccal-labial front side wall **104**, bottom wall **108**, and lingual rear side wall **106** that will be positioned against tooth tissue to be bleached during use. At least a portion of inner surface **103** includes one or more bleaching agent destabilizers. In one embodiment, the destabilizer may be compounded with the moisture resistant (e.g., polymeric) material from which the tray **100** is formed. In such an example, the destabilizer is distributed substantially evenly throughout the material from which tray **100** is formed, so that at least some destabilizer is present on inner treatment surface **103**. In another embodiment, the destabilizer may be applied to at least a portion of inner surface **103**, for example, by spraying, brushing, or otherwise applying the destabilizer onto the inner treatment surface **103**. Advantageously, the destabilizer may be present on at least that portion of inner surface **103** corresponding to surfaces of the teeth to be bleached. For example, the destabilizer may be present on at least the lower portion of buccal-labial front side wall **104** nearest bottom wall **108**, which

corresponds to the labial surface of the teeth to be bleached. Destabilizers may advantageously be absent from any portions of the tray designed to contact gingival tissue, where no bleaching is to take place.

[0029] The one or more bleaching agent destabilizers act to destabilize the peroxide dental bleaching agent during use. When peroxides are destabilized they more rapidly release free radicals, which cause tooth bleaching. For example, it is believed that peroxide dental bleaching agents are destabilized to form predominantly hydroxyl (HO.) free radicals, although peroxyl (.OOH), super oxide (.O), and super dioxide (.OO) free radicals may also be formed. Upon decomposition, which is accelerated by the bleaching agent destabilizer, these free radicals are more easily able to pass into the tooth enamel to the location of tooth stains as compared to the larger peroxide (H_2O_2) molecules, which may have increased difficulty passing through tight spaces of the enamel to stain locations because of their larger size. The bleaching agent destabilizer is advantageously retained on at least inner treatment surface **103** of the tray or strip prior to use, and upon contact with a peroxide dental bleaching agent in the presence of water; the destabilizer becomes activated, resulting in formation of free radicals from the peroxide for increased bleaching effect.

[0030] One class of bleaching agent destabilizers includes transition and/or alkaline earth metal ions. Non-limiting examples of suitable metal ions include magnesium ions, iron ions, titanium ions, cobalt ions, nickel ions, copper ions, platinum ions, tin ions, zinc ions, manganese ions, chromium ions, silver ions, aluminum ions, and combinations thereof. Magnesium and/or iron ions are particularly preferred. Another class of bleaching agent destabilizer includes enzymes, particularly organo-metallic enzymes containing transition metals, such as iron. Examples include "peroxidase" and "catalase", which is described more particularly in U.S. Pat. No. 6,485,709 to Banerjee et al., herein incorporated by reference with respect to its disclosure of organo-metallic enzymes.

[0031] One or more bleaching agent destabilizers including the above metal ions in available form and/or organo-metallic enzymes are preferably collectively included in an amount in a range of about 0.01% to about 20% by weight of the polymeric material, more preferably in a range of about 0.05% to about 10% by weight, and most preferably about 0.1% to about 5% by weight. Examples of suitable metal compounds include iodides, nitrates, chlorates, borates, perchlorates, and perborates of suitable metal cations. Preferred specific compounds include MgO, ferric sulfate, ferric chloride, MnO_2, and TiO_2. Less preferred bleaching agent destabilizers include elemental metals (e.g., iron, silver, platinum, copper, magnesium, titanium, cobalt, nickel, tin, zinc, chromium, aluminum, and/or manganese in powder form). Of course, any other metal ions mentioned herein may also be used in elemental form. Another class of bleaching agent destabilizers that may be used include iodine salts (e.g., potassium iodide and/or sodium iodide).

[0032] Many of the metal ion containing compounds are believed to react with the peroxide bleaching agent according to Fenton's Reaction, for example, ferric Fe^{2+} ions react to form ferrous Fe^{3+} ions in the presence of peroxide, releasing oxygen free radicals. During the course of the reaction, the peroxide is regenerated, allowing more ferric ions to react, resulting in production of more oxygen free radicals.

[0033] FIG. **2**A illustrates an alternative non-custom dental bleaching tray **200** that includes anatomical structural features that allow tray **200** to more closely conform to a person's teeth during use. Body **202** includes a buccal-labial front side wall **204**, a bottom wall **208**, and a lingual side wall **206** connected to bottom wall **208** at an opposite side relative to buccal-labial wall **204**. An inner treatment surface **203** is defined by interior portions of bottom wall **208**, buccal-labial front side wall **204**, and lingual side wall **206**. Illustrated tray **200** is sized and configured for placement over a person's upper dental arch. As illustrated, lingual wall **206** may advantageously include a notch **205**, which allows the non-custom tray **200** to more easily spread open or compress in the area of the incisors. This is helpful in allowing the lingual wall **206** of the non-custom tray **200** to more easily conform to differently-sized dental arches. Bottom wall **204** includes an abrupt reduction in width positioned at locations **210** corresponding to a transition between posterior teeth (i.e., bicuspids and molars) and anterior teeth (i.e., canines and incisors). Bottom wall **208** also advantageously includes two v-shaped indentations **216** for insertion into the depression between the occlusal peaks of the posterior teeth (i.e., the bicuspids and molars).

[0034] Similar to tray **100**, at least a portion of inner surface **203** of tray **200** includes one or more bleaching agent destabilizers. In a preferred example, the one or more dental bleaching agent destabilizers may be compounded with the moisture resistant polymeric material from which the tray **200** is formed. In such an example, the destabilizers may be distributed substantially evenly throughout the material from which tray **200** is formed, so that at least some destabilizer is present on inner treatment surface **203**. Alternatively, one or more bleaching agent destabilizers may be applied (e.g., after molding or otherwise forming tray body **202**) to at least a portion of inner treatment surface **203** where dental bleaching composition will be applied during use, and which surfaces of the tray will be placed against tooth tissues to be bleached during use.

[0035] FIG. **2**A is an exploded view showing the dental bleaching tray **200** in combination with a corresponding optional outer support tray **250** that is complementarily shaped so as to be capable of receiving the dental bleaching tray **200** in a nested configuration (see FIG. **2**B). The outer support tray **250** may include the same anatomical features as tray **200** in order to provide a closer fit. The outer support tray **250** advantageously includes a handle **252** extending outwardly from a central portion of the buccal-labial front wall in order to facilitate gripping by the user during placement of the dental bleaching tray **200** over the person's teeth.

[0036] In FIG. **2**B, dental bleaching tray **200** is nested within outer support tray **250** so as to form a dental tray assembly **255**. The handle **252** extends beyond the buccal-labial wall of tray **200** in order to facilitate placement and removal of the outer support tray **250** after placement of tray **200** over the person's teeth.

[0037] FIG. **3** illustrates an exemplary dental bleaching strip **400** which is formed from a polymeric material. Dental bleaching strip **400** is initially substantially rectangular and includes a planar surface **402** which can be positioned adjacent the teeth to be bleached and folded along the incisal edge of the teeth so as to cover the labial and incisal tooth surfaces. Depending on the position of the fold during placement, a portion (or substantially all) of the lingual tooth surfaces may also be covered by the strip **400** once placed. At least a portion of planar surface **402** defines an inner treatment surface cor-

responding to portions of surface **402** which are positioned adjacent to particularly the labial teeth surfaces during use.

[0038] At least a portion of inner planar surface **402** oriented toward a person's tooth surfaces includes one or more bleaching agent destabilizers. In a preferred example, the one or more dental bleaching agent destabilizers may be compounded with the moisture resistant polymeric material from which the strip **400** is formed. In such an example, the destabilizers may be distributed substantially evenly throughout the material from which strip **400** is formed, so that at least some destabilizer is present on planar treatment surface **402**. Alternatively, one or more bleaching agent destabilizers may be applied (e.g., after forming of strip barrier layer **400**) to at least a portion of inner treatment planar surface **402** where dental bleaching composition will be applied during use and which surfaces of the strip will be placed against tooth tissues to be bleached during use.

[0039] Although conventional strips are less effective in bleaching teeth relative to tray shaped barrier layers because strips tend to readily slip off and/or become mangled before treatment is complete, an improved dental bleaching strip can be provided according to the present invention by providing a bleaching agent destabilizer compounded within or otherwise disposed on an inner treatment surface of the strip. Such strips may provide for improved bleaching as the destabilizer acts to promote formation of active bleaching free radicals from the peroxide bleaching agent, which may be expected to result in faster bleaching, at least partially counteracting the disadvantages (i.e., tendency to slip off and/or mangle) of strips.

[0040] Any dental tray or strip according to the invention may be provided separately from a dental bleaching composition, which is introduced into the tray (e.g., adjacent the tray's inner treatment surface) or applied onto the strip by the user immediately prior to use so that there is no contact between the bleaching agent destabilizer of the barrier layer and the bleaching composition until treatment begins. In one alternative embodiment, it may be possible to prefill a tray or preapply a dental bleaching composition to a strip if the bleaching composition is anhydrous. The anhydrous dental bleaching composition may be disposed directly in contact with the barrier layer, and will not react prematurely because of the anhydrous nature of the bleaching composition. As soon as water is added to the system (e.g., when contacted by saliva by placing the pre-filled tray or pre-applied strip on the teeth), reaction between the destabilizer and bleaching agent will begin. Embodiments including an anhydrous dental bleaching composition may advantageously be sealed within a protective package to prevent absorption of water from the surrounding air during shipment and storage.

[0041] Another alternative embodiment may include an anhydrous adhesive composition (e.g., including polyvinyl pyrollidone as an adhesive agent) that also includes a bleaching agent destabilizer (e.g., potassium iodide). The adhesive destabilizing composition may be coated over the barrier layer (e.g., as a thin layer or film). It is important to note that such a composition including the bleaching agent destabilizer is applied to a region of the barrier layer corresponding to the tooth surfaces to be bleached. In other words, if the composition is not applied over substantially the entire interior surface of the barrier layer tray or strip, it is at least applied to that portion of the barrier layer which in use is positioned against the tooth surfaces to be bleached (e.g., at least the labial tooth surface). It is not necessary to apply the bleaching agent destabilizer to regions of the barrier layer which will be positioned against gum tissue during use. In fact it may be preferable in some embodiments to ensure that no bleaching agent destabilizer is present in regions of the barrier layer which will be positioned against gingival tissue so as to prevent reaction with peroxide bleaching agents adjacent the gingival tissue, which may otherwise cause discomfort and soreness. Of course, in embodiments where the destabilizer is compounded within the material of the barrier layer this may be impractical, although discomfort to gingival tissues may be prevented by limiting application of the bleaching composition to regions of the barrier layer corresponding to tooth surfaces to be bleached.

[0042] In other words, it may be preferred to apply the bleaching composition so that substantially no bleaching composition is applied adjacent any part of the barrier layer that will be positioned adjacent the gingival tissue, so that the bleaching agent and the destabilizer are only present together at portions of the tray corresponding to tooth surfaces to be bleached. In embodiments where the destabilizer is applied as a film or composition layer, it may be preferable to maintain any portions of the barrier layer which will be positioned adjacent to gingival tissue so that they are substantially free of the bleaching agent destabilizers, and that the destabilizer film or layer is only applied to those portions of the barrier layer corresponding to tooth surfaces to be bleached (e.g., at least the labial tooth surface). In other words, in any embodiment, the bleaching agent and the destabilizer may be present together only at those portions of the tray corresponding to tooth surfaces to be bleached. At portions of the tray that will be positioned adjacent to gingival tissue during use, only one or the other (or neither) of the bleaching agent destabilizer and the bleaching agent are present so as to prevent discomfort and soreness.

[0043] In embodiments where the adhesive destabilizer composition is anhydrous, a peroxide bleaching agent may also be included, so long as no water is present so as to prevent premature reaction between the bleaching agent destabilizer and the peroxide bleaching agent. Alternatively, a bleaching composition (e.g., an aqueous gel) may be applied over the layer or film adhesive layer just prior to use. The water within the bleaching composition and/or saliva within the user's mouth causes the bleaching agent destabilizer to be activated in the presence of the bleaching agent.

[0044] In another alternative embodiment, a non-custom dental tray or strip according to the invention may be preloaded with a dental bleaching composition. In order to prevent premature contact between the bleaching agent destabilizer and bleaching composition, the tray or strip further includes a protective rupturable membrane disposed between the barrier layer and the bleaching composition. The membrane may be configured to be rupturable subsequent to placement of the tray over the person's teeth. For example, a rupturable membrane of a tray or strip bleaching device may be configured to rupture upon biting, bending and/or folding of the barrier layer and membrane. Such a rupturable membrane may comprise any rupturable layer that is disposed between the bleaching composition and the tray or strip including a bleaching agent destabilizer. Examples of suitable materials include a protective coating layer of high molecular weight polyethylene glycol, a di-para-xylene coating layer, and/or a wax coating. Di-para-xylene is available commercially as Parylene from Parylene Coating Services, Inc., located in Katy, Tex. Such coatings may serve to simply separate the bleaching composition from the barrier layer

during storage and shipment, and the coating membrane is ruptured upon biting, bending, and/or flexing of the tray or strip. The rupturable membrane layer may be water-degradable so as to dissolve, degrade, or become dispersed upon contact with moisture (e.g., saliva).

[0045] Such a tray or strip may be provided within a sealed container or package to protect the tray or strip, the bleaching composition, and rupturable membrane from contaminants and/or premature rupture during storage, transport, and prior to use. FIG. **4** shows a first tray assembly **355** configured for placement over an upper dental arch and a second tray assembly **355'** configured for placement over a lower dental arch sealed within protective package **356**. Each tray **300** and **300'** includes a bleaching composition **354** pre-loaded therein. Protective package **356** includes a rigid support layer **358** and a peelable cover **360**. Each tray assembly **355** and **355'** may optionally include an additional removable protective layer (not shown) placed adjacent to the bleaching composition **354** for additional protection. When it is desired to use the dental bleaching tray devices, the peelable cover **360** is removed and the tray assemblies **355** and **355'** are removed or separated from support layer **358**.

[0046] FIG. **5** illustrates a cross-sectional view through tray assembly **355** of FIG. **4**, including tray **300** and outer support tray **350**, perhaps best illustrating protective rupturable membrane **357** disposed adjacent to inner treatment surface **303** of tray **300**.

[0047] Another embodiment may include a multi-use tray, for example a custom dental tray formed by vacuum forming a sheet of moisture resistant thermoplastic polymer material over a stone cast of a person's teeth, after which the custom tray may be cut out. Such custom trays can be very comfortable to wear as they provide an excellent fit to the user's dentition. A bleaching agent destabilizer (e.g., a ferric salt) may be compounded with the tray material or otherwise provided so that the bleaching agent destabilizer is present on the interior treatment surface of the tray. During use, the user applies a bleaching composition into the tray, and then places the tray over the teeth for bleaching treatment. The bleaching agent destabilizer, for example, a ferric salt, is oxidized during use so as to form ferrous ions. Because at least some of the bleaching agent destabilizer will likely remain after use, the custom tray may be used multiple times before all the bleaching agent destabilizer has been consumed. Once all bleaching agent destabilizer has been consumed, the custom tray may still be used as a conventional custom bleaching tray, although it will no longer provide the increased bleaching effect afforded by the bleaching agent destabilizer.

[0048] The trays and strips may be used with any known dental bleaching composition. Exemplary bleaching compositions include a peroxide dental bleaching agent. The bleaching composition may comprise a sticky viscous gel, a less viscous gel, a highly viscous putty, or a substantially solid composition that is less adhesive prior to being moistened with saliva or water but that becomes more sticky and adhesive when moistened.

[0049] According to one embodiment, the barrier layer comprises a thin (e.g., about 1 mm or less), flexible membrane formed from a polymeric or other moisture-resistant material. Polymeric materials are preferred. In one embodiment, the barrier layer comprises silicone. In another, it comprises ethyl vinyl acetate and polypropylene. According to another embodiment, it may be formed of a polyolefin or similarly moisture-resistant material, such as wax, paraffin, ethylene-vinyl acetate copolymer (EVA), ethylene-vinyl alcohol copolymer (EVAL), polycaprolactone (PCL), polyvinyl chloride (PVC), polyesters, polycarbonates, polyamides, polyurethanes or polyesteramides. Examples of suitable polyolefins for use in making the barrier layer include, but are not limited to, polyethylene (PE), high density polyethylene (HDPE), low density polyethylene (LDPE), ultra low density polyethylene (ULDPE), polypropylene, and polytetrafluoroethylene (PTFE) (e.g., TEFLON). An example of a suitable polyester for use in making the barrier layer includes, but is not limited to, polyethylene terephthalate (PET), an example of which is MYLAR, sold by DuPont. An example of a suitable polyurethane barrier material is a polyurethane film manufactured by ArgoTech, which is located in Greenfield, Mass. The barrier layer may comprise a polymeric blend and/or multiple layers comprising two or more of the foregoing materials. Plasticizers, flow additives, and fillers known in the art can be used as desired to modify the properties of any of the foregoing polymers used to form the barrier layer. The forgoing listing of polymeric materials is not meant to be exhaustive, as numerous other polymeric materials may be used.

[0050] Other materials that can act as a barrier layer include metal foil, cellulosic ethers, cellulose acetate, polyvinyl acetate, polyvinyl alcohol, shellac, and chemical or light-cure materials (e.g., methacrylate or acrylate resins). Examples of useful cellulosic ethers that can be used to form a barrier layer include, but are not limited to, ethyl cellulose, propyl cellulose, isopropyl cellulose, butyl cellulose, t-butyl cellulose, and the like. Although non-polymeric moisture resistant materials, e.g., metal foil, may be used, polymeric materials are preferred.

[0051] Silicone and silicone like materials (i.e., materials exhibiting similar physical characteristics) are one preferred class of polymeric materials for forming the barrier layer because of their excellent adaptability, flexibility, softness, elasticity, and resiliency. Exemplary suitable two-part silicone materials are available from Shin-Etsu Silicones of America, located in Akron, Ohio. One preferred material is KEG2000-50A/B, the physical properties of which are described in the table below. Various other Shin-Etsu silicone products and silicone materials from other suppliers can also be used.

Property	Value
Hardness - Shore-A	52
Tensile Strength - MPa	11.1
Elongation - %	580
100% Modulus - Mpa	1.72
Tear Strength - kN/m	40
Comp Set 22 h/302° F.-1 h/302° F.	31
Comp Set 22 h/302° F.-4 h/392° F.	8
Linear Shrinkage	2.6
Specific Gravity	1.13
Viscosity - Part A-Pa · s	1700
Viscosity - Part B-Pa · s	1600

[0052] For example, a silicone material may initially comprise a two-part composition including a first part comprising one or more siloxanes and a second part including an activator. Upon mixing the two liquid parts together, the siloxane molecules polymerize and cross-link so as to form a polysiloxane. Heat may be applied (e.g., by heating the mold) to accelerate polymerization of the silicone material. For

example, part A and part B of the raw silicone precursor material are mixed together, which causes the material to begin to polymerize. For many exemplary silicone materials, this reaction could take 2-6 weeks to completely cure at room temperature. Heating the mixture significantly increases the rate at which the material polymerizes. For example, according to one method, the material is heated to 375° F. so as to cause the material to polymerize in a matter of seconds. Actual polymerization time depends on the thickness of the tray or strip being formed. Silicone trays and/or strips may also be formed by other methods, for example with a two part silicone in which polymerization is activated by mixing and/or by compression.

[0053] Silicone polymeric materials include a platinum and/or tin catalyst within one or both parts of the composition to assist with polymerization. Advantageously, residual catalyst is present within the material after the tray or strip has been formed. Residual platinum and/or tin catalyst disposed throughout the material, including on the inner treatment surface of the tray or strip, can also act as a bleaching agent destabilizer, acting to produce free radicals from the peroxide bleaching agent upon contact of the barrier layer with a peroxide bleaching composition. Although platinum is a less preferred destabilizer because of its generally higher cost, it is within the scope of the present invention to utilize platinum when present. As the platinum and/or tin may be included in small, silicone-catalyzing amounts (e.g., typically less than 1000 ppm, more typically less than 100 ppm), it may be advantageous to include an additional, more preferred destabilizer, for example magnesium and/or iron in addition to the residual platinum and/or tin, in order to boost the overall destabilizing effect.

[0054] Styrene-ethylene-butylene-styrene (SEBS), and/or VERSAflex, a proprietary thermoplastic elastomer alloy exhibiting elasticity and other properties similar to silicone, are examples of silicone-like materials. A suitable example of a SEBS material is SEBS TPE 45A, available from various providers. Physical properties for SEBS TPE 45A are summarized in the table below. Various other SEBS products may also be used in forming a polymeric moisture resistant barrier layer.

Property	Value
Density (g/cm^3)	0.94
Surface Hardness- Shore A	45
Tensile Strength (MPa)	6
Flexural Modulus (GPa)	0.02
Notched Izod (kJ/m)	1.06+
Linear Expansion (/° C. × 10^{-5})	16
Elongation at Break (%)	800
Water Absorption (%)	0.3
Oxygen Index (%)	19
Melting Temp. Range (° C.)	200-240
Mold Shrinkage (%)	1.5
Mold Temp. Range (° C.)	50-70

[0055] Several suitable VERSAFLEX TPE materials are available from GLS Corporation, located in McHenry, Ill. Preferred VERSAFLEX materials include VERSAFLEX CL30 and VERSAFLEX CL40, properties of each of which are summarized in the table below. Various other VERSAFLEX products from GLS Corporation can also be used.

	Product		
Property	CL30	CL40	Test Method
Shore A Hardness, 10 sec delay	30	43	ASTM D2240
Specific Gravity	0.89	0.89	ASTM D792, 23/23° C.
Tensile Strength	6619 kPa	5929 kPa	ASTM D412-Die C, 2 hrs, 23° C.
Elongation at Break	780%	690%	ASTM D412-Die C, 2 hrs, 23° C.
100% Modulus	689 kPa	1379 kPa	ASTM D412-Die C, 2 hrs, 23° C.
300% Modulus	1448 kPa	2413 kPa	ASTM D412-Die C, 2 hrs, 23° C.
Tear Strength	19 kN/m	23 kN/m	ASTM D624
Melt Flow Rate @ 190° C., 2160 g	18 g/10 min	13 g/10 min	ASTM D 1238
Melt Flow Rate @ 200° C., 5000 g	108 g/10 min	38 g/10 min	ASTM D 1238
Apparent Viscosity @ 200° C. 11170/sec	15 Pa-s	16 Pa-s	ASTM D 3835
Compression Set, 22 hrs @ RT	11%	12%	ASTM D 395B

[0056] Preferred dental bleaching trays are characterized by wall thicknesses of no more than about 1 mm, more preferably between about 0.03 mm and about 1 mm, and most preferably between about 0.1 mm and about 0.5 mm. Wall thicknesses greater than about 1 mm are significantly less useful as a comfortable dental bleaching tray, as the thickness of the tray begins to seriously interfere with the normal relaxed position of the occlusal tooth surfaces when wearing such a tray (i.e., the tray(s) get in the way between teeth of opposite dental arches, preventing the user from completely closing their jaw), making the tray significantly less comfortable than a tray with wall thicknesses that are no more than about 1 mm. For this same reason, existing mouth guards formed of silicone have little or no use as a comfortable dental treatment tray as their wall thickness is typically greater than 2 mm, and more typically about 4 mm so as to provide a cushioning effect to the teeth when accepting a blow to the mouth or jaw. Similarly, the inventive dental bleaching trays would be unacceptable for use as a mouth guard, as their thin walls provide little or no protection to the teeth against such blows.

[0057] The dental bleaching trays according to the invention can be designed to be worn for any desired time period. Due to the extremely comfortable fit between the inventive dental bleaching trays and the person's teeth, it is possible to wear such trays for extended periods of time as desired. The dental bleaching trays can be worn for as little as a few minutes or as long as several hours. By way of example, not limitation, a typical bleaching session of fast duration may last from about 10 to about 30 minutes; a bleaching session of intermediate duration may last from about 30 minutes to about 2 hours; and a bleaching session of long duration, including overnight bleaching while a person is sleeping, may last from about 2 hours to about 12 hours.

[0058] When used in combination with a sticky bleaching composition, dental bleaching trays may possibly be worn while performing normal daily activities, such as talking, drinking, smoking, coughing, smiling, frowning, grimacing, or while sleeping. Dental bleaching trays according to the invention may be worn over a person's upper dental arch, lower dental arch, or both simultaneously. Although trays provide an improved fit as compared to strips, it is of course within the scope of the invention to provide dental bleaching strips which can also be used to provide similar treatment. Such strips may be expected to be worn for similar ranges of time as described above, and when used with an initially dry bleaching composition that becomes very sticky upon contact with water, may even be worn while engaging in the above described activities as the bleaching composition (e.g., a substantially dry bleaching composition) more effectively holds the strip in place against the tooth tissues to be bleached.

[0059] FIG. **6**A illustrates a person **375** placing a dental bleaching assembly **355** over the person's upper dental arch. The outer support tray helps in placing the inner bleaching tray over the teeth. FIG. **6**B illustrates a dental bleaching tray **300** in place over the person's upper dental arch and a dental bleaching tray **300'** over the lower dental arch, both outer support trays having been removed.

[0060] To remove the dental bleaching tray after a desired time period, the user simply grasps a corner or portion of the tray and pulls it off the teeth. Any residual bleaching composition that remains adhered to the person's teeth can be removed by washing or flushing with water and/or by brushing.

EXAMPLES OF THE PREFERRED EMBODIMENTS

[0061] Following are examples of polymeric compositions that may be used to manufacture dental bleaching trays according to the invention. The exemplary formulations and manufacturing conditions are given by way of example, and not by limitation. Unless otherwise indicated, all percentages are by weight.

Example 1

[0062] A composition for injection molding a silicone dental treatment tray was formed from Shin-Etsu's KEG2000-50A/B two part thermoset silicone material. Part A containing the activator/hardener had a viscosity of about 1700 Pa-s, while part B containing the siloxane had a viscosity of about 1600 Pa-s. At least one part included a platinum catalyst.

[0063] The two parts of the silicone composition were pumped out of storage drums through hoses to a static mixing head where the two parts were mixed together. The mixed silicone material exits the static mixer and was forced into the screw and barrel of the injection molding machine. The mixed silicone material was injected into the heated mold (e.g., about 375° F.), at which point the material quickly polymerized. The tray was removed from the hot mold after polymerization was substantially complete. Exemplary formed trays exhibited excellent adaptability, flexibility, elasticity, and softness, while also being resilient. The molded trays were translucent, had a Shore A durometer hardness of about 50, an elasticity of about 580%. Trays having wall thicknesses of about 0.004 inch (0.10 mm), 0.006 inch (0.15 mm), 0.008 inch (0.2 mm), 0.01 inch (0.25 mm) and 0.014 inch (0.36 mm), respectively, were formed. It is believed that the residual platinum catalyst content within the finished tray was less than 1000 ppm, more likely less than 100 ppm. The presence of residual platinum catalyst within the silicone material provided available platinum ions to act as a bleaching agent destabilizer when contacted with a peroxide dental bleaching agent.

Example 2

[0064] A composition for injection molding a dental treatment tray was formed from SEBS TPE 45A material. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. Exemplary formed SEBS trays exhibited excellent adaptability, flexibility, elasticity, and softness, while also being resilient, similar to the silicone tray of Example 1. The molded trays were translucent, had a Shore A durometer hardness of about 45, an elasticity of about 800% and a wall thickness of about 0.020 inch (0.5 mm). The trays were found to be very comfortable when worn over a person's dental arch, with excellent adaptability, flexibility, elasticity, softness, and resiliency. A bleaching agent destabilizer (e.g., about 0.1 percent to about 5 percent by weight) may be compounded with the SEBS material prior to molding so that the finished trays include the bleaching agent destabilizer on the inner surface of the tray.

Example 3

[0065] A composition for injection molding a dental treatment tray is formed from VERSAFLEX CL30. The heated TPE material is pumped so as to be forced into the screw and barrel of the injection molding machine. The material is injected into the mold. The cooled tray is removed from the mold. Exemplary formed VERSAFLEX CL30 trays exhibit excellent adaptability, flexibility, elasticity, and softness, while also being resilient, similar to the silicone tray of Example 1. The molded trays are translucent, have a Shore A durometer hardness of about 30, an elasticity of about 780% and a wall thickness of about 0.020 inch (0.5 mm). The trays are very comfortable when worn over a person's dental arch, with excellent adaptability, flexibility, elasticity, softness, and resiliency A bleaching agent destabilizer (e.g., about 0.1 percent to about 5 percent by weight) may be compounded with the VERSAFLEX material prior to molding so that the finished trays include the bleaching agent destabilizer on the inner surface of the tray.

Example 4

[0066] A composition for injection molding a dental treatment tray is formed from VERSAFLEX CL40. The heated

TPE material is pumped so as to be forced into the screw and barrel of the injection molding machine. The material is injected into the mold. The cooled tray is removed from the mold. Exemplary formed VERSAFLEX CL40 trays exhibit excellent adaptability, flexibility, elasticity, and softness, while also being resilient, similar to the silicone tray of Example 1. The molded trays are translucent, have a Shore A durometer hardness of about 40, an elasticity of about 690% and a wall thickness of about 0.020 inch (0.5 mm). The trays are very comfortable when worn over a person's dental arch, with excellent adaptability, flexibility, elasticity, softness, and resiliency A bleaching agent destabilizer (e.g., about 0.1 percent to about 5 percent by weight) may be compounded with the VERSAFLEX material prior to molding so that the finished trays include the bleaching agent destabilizer on the inner surface of the tray.

Example 5

[0067] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Ferric sulfate	2%

[0068] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the ferric sulfate bleaching agent destabilizer on the inner surface of the tray.

Example 6

[0069] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Ferric chloride	2%

[0070] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the ferric chloride bleaching agent destabilizer on the inner surface of the tray.

Example 7

[0071] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Magnesium powder	2%

[0072] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental magnesium bleaching agent destabilizer on the inner surface of the tray.

Example 8

[0073] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Iron powder	2%

[0074] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental iron bleaching agent destabilizer on the inner surface of the tray.

Example 9

[0075] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Copper powder	2%

[0076] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental copper bleaching agent destabilizer on the inner surface of the tray.

Example 10

[0077] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Nickel powder	2%

[0078] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The

finished trays included the elemental nickel bleaching agent destabilizer on the inner surface of the tray.

Example 11

[0079] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Aluminum powder	2%

[0080] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental aluminum bleaching agent destabilizer on the inner surface of the tray.

Example 12

[0081] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Chromium powder	2%

[0082] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental chromium bleaching agent destabilizer on the inner surface of the tray.

Example 13

[0083] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Zinc powder	2%

[0084] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental zinc bleaching agent destabilizer on the inner surface of the tray.

Example 14

[0085] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 450	98%
Titanium powder	2%

[0086] All fractions are by weight. ELVAX 450 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental titanium bleaching agent destabilizer on the inner surface of the tray.

Example 15

[0087] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 250	98%
Magnesium powder	2%

[0088] All fractions are by weight. ELVAX 250 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental magnesium bleaching agent destabilizer on the inner surface of the tray.

Example 16

[0089] A composition for injection molding a dental treatment tray was formed by combining and mixing the following materials:

ELVAX 720	98%
Magnesium powder	2%

[0090] All fractions are by weight. ELVAX 720 is an EVA polymeric material available from Dupont. The heated material was pumped so as to be forced into the screw and barrel of the injection molding machine. The material was injected into the mold. The cooled tray was removed from the mold. The finished trays included the elemental magnesium bleaching agent destabilizer on the inner surface of the tray.

[0091] Following is an example of a dental bleaching composition that can be used in combination with dental bleaching trays or strips including a bleaching agent destabilizer. The dental bleaching composition may be pre-loaded in a tray or pre-applied to a strip.

Example 17

[0092] A sticky, viscous dental bleaching composition was prepared by mixing together the following components:

Water	22.5%
EDTA Disodium	0.1%

-continued

Carbamide Peroxide	18.5%
Sucralose 25% solution	0.75%
Glycerine	41.6%
Carbopol 974	5.3%
Sodium Hydroxide 50% solution	2.25%
Polyvinyl Pyrrolidone (M.W. = 1.3 million)	2%
Carboxymethyl Cellulose	4%
Watermelon Flavor	3%

[0093] All fractions are by weight. A bite ruptureable membrane is positioned adjacent the inner treatment surface of a tray shaped or strip shaped barrier layer. A bead of dental bleaching composition is then spread along the ruptureable barrier layer adjacent the dental bleaching tray. The bleaching composition may be positioned adjacent the labial-buccal wall of the tray, as illustrated in FIG. **5**. In the case of a strip, the dental bleaching composition is applied evenly over one side of the strip shaped barrier layer, with the rupturable membrane between the composition and the barrier layer. During placement and/or use the rupturable membrane is broken, contacting the composition to the barrier layer. Upon contact of the bleaching composition with the barrier layer, the peroxide dental bleaching agent is destabilized so as to accelerate production of free radicals. The trays and strips reliably adhere to tooth tissue, and exhibit excellent comfort and adhesiveness.

[0094] Additional exemplary dental bleaching compositions, and methods for making such compositions, which may be used with devices according to the invention are disclosed in U.S. Pat. No. 5,376,006; U.S. Pat. No. 5,785,527; U.S. Pat. No. 5,851,512; U.S. Pat. No. 5,858,332; U.S. Pat. No. 5,985,249; U.S. Pat. No. 6,306,370; U.S. Pat. No. 6,309,625; U.S. Pat. No. 6,312,671; U.S. Pat. No. 6,322,774; U.S. Pat. No. 6,368,576; U.S. Pat. No. 6,387,353; U.S. Pat. No. 6,500,408; U.S. Pat. No. 6,503,485 and U.S. patent application Ser. No. 11/460,016 filed Jul. 26, 2006. For purposes of disclosing dental bleaching compositions, and methods of making such compositions, the foregoing patents and application are incorporated herein by reference.

[0095] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A dental treatment device for use in applying a dental treatment composition to a person's teeth and/or gums, comprising:

a moisture-resistant barrier layer comprised of a blend of wax and a polymeric material; and

a substantially solid dental treatment composition disposed adjacent to the moisture-resistant barrier layer and comprising at least one adhesive agent and at least one active agent, the substantially solid dental treatment composition being substantially dry to the touch or less adhesive prior to being moistened with saliva or water adapted to become more sticky and adhesive when moistened with saliva or water.

2. A dental treatment device as recited in claim **1**, wherein the moisture-resistant barrier layer is a strip.

3. A dental treatment device as recited in claim **2**, wherein the strip is flexible so as to wrap around a person's teeth and assume a tray shape when worn over the person's teeth during use.

4. A dental treatment device as recited in claim **1**, wherein the moisture-resistant barrier layer is tray shaped.

5. A dental treatment device as recited in claim **1**, wherein the moisture-resistant barrier layer comprises a blend of paraffin wax and a polyolefin.

6. A dental treatment device as recited in claim **5**, wherein the moisture-resistant barrier layer comprises a blend of paraffin wax and polyethylene.

7. A dental treatment device as recited in claim **5**, wherein the moisture-resistant barrier layer comprises a blend of paraffin wax and polypropylene.

8. A dental treatment device as recited in claim **1**, wherein the moisture-resistant barrier layer further comprises at least one material selected from the group consisting of plasticizers, flow additives, and fillers.

9. A dental treatment device as recited in claim **1**, wherein the dental treatment composition comprises a dental bleaching agent.

10. A dental treatment device as recited in claim **1**, wherein the at least one adhesive agent is selected from the group consisting of polyvinyl pyrrolidone and carboxymethylcellulose.

11. A dental treatment device as recited in claim **1**, wherein the moisture-resistant barrier layer further comprises a bleaching agent destabilizer compounded with and/or disposed on the inner treatment surface of the barrier layer.

12. A dental treatment device for use in applying a dental treatment composition to a person's teeth and/or gums, comprising:

a moisture-resistant barrier layer comprised of a blend of paraffin wax and a polymeric material, wherein the moisture-resistant barrier layer is a flexible strip adapted as to wrap around a person's teeth and assume a tray shape when worn over the person's teeth during use; and

a substantially solid dental treatment composition disposed adjacent to the moisture-resistant barrier layer and comprising at least one adhesive agent and at least one active agent, the substantially solid dental treatment composition being substantially dry to the touch or less adhesive prior to being moistened with saliva or water adapted to become more sticky and adhesive when moistened with saliva or water.

13. A dental treatment device as recited in claim **12**, wherein the polymeric material comprises a polyolefin.

14. A dental treatment device as recited in claim **13**, wherein the polyolefin comprises polyethylene.

15. A dental treatment device as recited in claim **13**, wherein the polyolefin comprises polypropylene.

16. A dental treatment device as recited in claim **12**, wherein the moisture-resistant barrier layer further comprises at least one material selected from the group consisting of plasticizers, flow additives, and fillers.

17. A dental treatment device as recited in claim **1**, wherein the dental treatment composition comprises a dental bleaching agent.

18. A dental bleaching device for use in applying a dental treatment composition to a person's teeth and/or gums, comprising:

a moisture-resistant barrier layer comprised of a blend of wax and a polymeric material, wherein the moisture-

resistant barrier layer is a flexible tray-like body adapted so as to wrap around a person's teeth when worn; and

a substantially solid dental treatment composition disposed adjacent to the moisture-resistant barrier layer and comprising at least one adhesive agent and at least one dental bleaching agent, the substantially solid dental treatment composition being substantially dry to the touch or less adhesive prior to being moistened with saliva or water adapted to become more sticky and adhesive when moistened with saliva or water.

19. A dental treatment device as recited in claim **18**, wherein the moisture-resistant barrier layer comprises a blend of paraffin wax and a polyolefin.

20. A dental treatment device as recited in claim **19**, wherein the moisture-resistant barrier layer further comprises at least one material selected from the group consisting of plasticizers, flow additives, and fillers.

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