

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
16 December 2010 (16.12.2010)

(10) International Publication Number  
**WO 2010/142013 A1**

(51) International Patent Classification:

A61N 5/06 (2006.01) A61C 7/08 (2006.01)  
A61N 5/067 (2006.01) A61C 7/00 (2006.01)

(21) International Application Number:

PCT/CA2009/000808

(22) International Filing Date:

8 June 2009 (08.06.2009)

(25) Filing Language:

English

(26) Publication Language:

English

(71) Applicant (for all designated States except US): **BI-OLUX RESEARCH LIMITED** [CA/CA]; 825 Powell Street, Suite 220, Vancouver, British Columbia V6A 1H7 (CA).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **BRAWN, Peter Robert** [CA/CA]; 1260 West Cordova Street, Vancouver, British Columbia V6C 3R4 (CA).

(74) Agents: **KONDOR, George F.** et al.; 480-The Station, 601 West Cordova Street, Vancouver, British Columbia V6B 1G1 (CA).

(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, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

(54) Title: METHOD AND DEVICE FOR ACCELERATING ORTHODONTIC TOOTH MOVEMENT

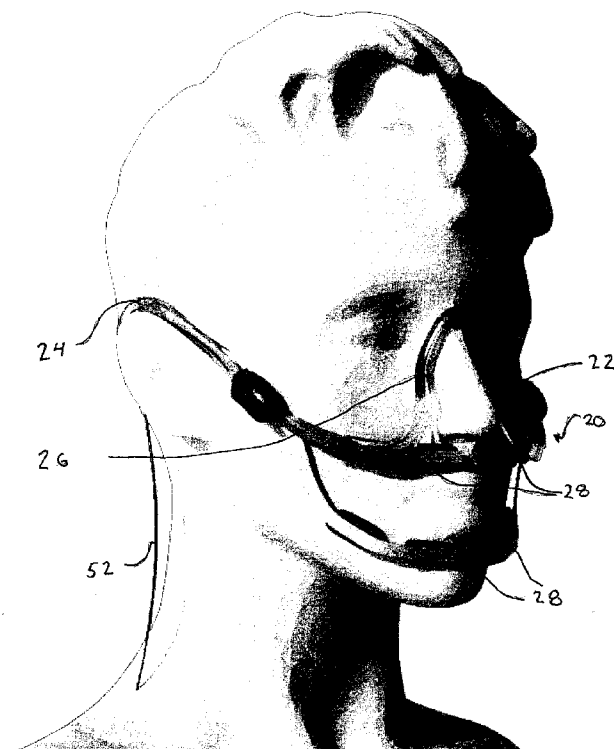


FIG. 1

(57) Abstract: A method for regulating or accelerating tooth movement during orthodontic treatment of a person by applying an effective repetitive dosage of light extra-orally to a selected region of the person's maxillary and mandibular alveolar bone. The repetitive dosage may be in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>. The light may have a wavelength in the range of about 585 nm to about 665 nm, or about 815 nm to about 895 nm. Light having a first wavelength may be applied to a first selected region of the alveolar bone, and light having a second wavelength may be applied to a second selected region of the alveolar bone to selectively regulate tooth movement during orthodontic treatment. An apparatus for applying light therapy extra-orally is also provided.

WO 2010/142013 A1

**METHOD AND DEVICE FOR ACCELERATING ORTHODONTIC  
TOOTH MOVEMENT**

Technical Field

- 5 [0001] This invention relates to methods and devices for orthodontics, and in particular to methods and devices for accelerating and/or improving tooth movement during orthodontic treatment.

Background

- 10 [0002] Orthodontics requires the movement of teeth through bone. By applying pressure to a tooth, bone may be broken down at a leading edge of the tooth to facilitate tooth movement. New bone is then created at a trailing edge of the tooth. Movement of teeth through bone is slow, thereby necessitating treatments of long duration in order to achieve the desired tooth  
15 position. Long-term orthodontic treatment may have an increased risk of root resorption, gingival inflammation and dental caries. Moreover, movement of teeth through bone may be uneven, as teeth may “tip” due to the force applied, i.e. the crown of the tooth may move in the desired direction more quickly than the root of the tooth, resulting in tipping of the tooth. It is often  
20 preferable for teeth to move “bodily” through the bone, i.e. in a more or less perpendicular orientation relative to the bone, without tipping or with only a low degree of tipping.

- [0003] Methods for increasing the rate of tooth movement without damage to the tooth and periodontium have been sought out. For example,  
25 acceleration of tooth movement may be produced by the local injection of prostaglandins, the active form of vitamin D3, and osteocalcin around the alveolar socket. These substances may increase the rate of tooth movement, but may also cause side effects such as local pain and discomfort for a patient during the process of injection.

- 30 [0004] An alternative strategy for increasing the rate of tooth movement is to improve bone regeneration. For example, light therapy has been found to be effective in the treatment of bone disorders and the biostimulation of bone and soft tissue, and may be effective in accelerating alveolar bone regeneration. Light can stimulate a variety of biological  
35 activities in cells and tissues that are compromised in function, for example by stimulating cytochrome C oxidase or nitric oxide synthase.

- 2 -

5 [0005] Phototherapy or light therapy treatment is typically administered by a physician or therapist who directs light from a hand-held light emitting device at an affected area. Light emitting devices can be difficult to position consistently over the affected area. Sometimes a tattoo is used to identify the affected area. However, even with a tattoo or other reference mark it may be difficult to consistently deliver light therapy treatments to an affected area.

10 [0006] Light therapy typically involves repeated treatments over at least several days. Thus, patients undergoing light therapy may be required to make multiple visits to a practitioner's office or clinic in order to complete a therapy regimen. Such repeated visits may be time consuming and/or expensive.

15 [0007] LEDs and other light sources suitable for generating light for light therapy can get hot when they operate. Such light sources can be inefficient at higher temperatures. Hot apparatus can also be uncomfortable or even dangerous to patients.

20 [0008] Apparatus for delivering light therapy to the dental and maxillofacial areas of a patient have been developed, for example as described in PCT publication numbers WO 2009/000075 and WO 2006/087633, both of which are incorporated by reference herein. However, there remains a need for light therapy apparatus which can deliver specifically targeted light therapy to flood desired regions of a patient's jawbone with light having desired characteristics.

25 [0009] There further remains a need for methods and apparatus that increase the velocity of tooth movement through bone in response to orthodontic treatment, to decrease treatment times for patients without undesirable side effects or pain. There is also a need for methods and apparatus that may be used to achieve a desired mode or quality of movement of teeth through the bone, e.g. bodily movement of teeth through bone, and which may be adjustable to permit tooth movement to be modulated at a  
30 desired specific location or locations within a patient's jaw region.

[0010] The foregoing examples of the related art and limitations related thereto are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

### Summary

**[0011]** The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope. In various  
5 embodiments, one or more of the above-described problems have been reduced or eliminated, while other embodiments are directed to other improvements.

**[0012]** In one embodiment, a method is provided for regulating tooth movement during orthodontic treatment of a person by applying an effective  
10 repetitive dosage of light extra-orally to a selected region of the person's maxillary and mandibular alveolar bone. The effective repetitive dosage may be in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>, and may have a wavelength in the range of about 585 nm to about 665 nm, or about 815 nm to about 895 nm. Light having a wavelength in the range of about 585 nm to about 665 nm may  
15 be used to promote the bodily movement of teeth. Light having a wavelength in the range of 815 nm to about 895 nm may be used to increase the velocity of teeth through the person's bone when the teeth are to be moved in a tipped orientation. Teeth in a region of the person's maxillary and mandibular alveolar bone to which light is not applied may be used as an anchor to  
20 facilitate movement of teeth in the selected region.

**[0013]** In another embodiment, a method for selectively regulating tooth movement during the orthodontic treatment of a person is provided. The method includes applying an effective repetitive dosage of light having a  
25 first wavelength extra-orally to a selected first region of the person's maxillary and mandibular alveolar bone, and applying an effective repetitive dosage of light having a second wavelength extra-orally to a selected second region of the person's maxillary and mandibular alveolar bone. The effective repetitive dosage of light may be in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>. The first wavelength may be in the range of about 585 nm to about 665 nm, and  
30 the second wavelength may be in the range of about 815 nm to about 895 nm.

**[0014]** In another embodiment, a method for stabilizing teeth of a person following completion of orthodontic treatment is provided. The method includes applying an effective repetitive dosage of light having a wavelength in the range of about 585 nm to about 665 nm extra-orally to a

- 4 -

selected region of the person's maxillary and mandibular alveolar bone when orthodontic treatment is fully or substantially complete. In another embodiment, the method includes applying an effective repetitive dosage of light having a wavelength in the range of about 815 nm to about 895 nm  
5 extra-orally to a selected region of the person's maxillary and mandibular alveolar bone when orthodontic treatment is fully or substantially complete.

[0015] In another embodiment, an apparatus for selectively regulating tooth movement during orthodontic treatment of a person is provided. The apparatus has a support sized and shaped to engage with features of a  
10 person's face, and a plurality of light sources associated with the support and configured to deliver light substantially uniformly extra-orally to selected regions of a person's maxillary and mandibular alveolar bone.

[0016] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to  
15 the drawings and by study of the following detailed descriptions.

#### Brief Description of Drawings

[0017] Exemplary embodiments are illustrated in referenced figures of the drawings. It is intended that the embodiments and figures disclosed  
20 herein are to be considered illustrative rather than restrictive.

[0018] FIG. 1 is an isometric view of an embodiment of a light therapy apparatus for providing light therapy to specified regions of a person's maxillary and mandibular alveolar bone.

[0019] FIG. 2 is a front view of the embodiment shown in FIG. 1.

25 [0020] FIG. 3 is a top view of the embodiment shown in FIG. 1.

[0021] FIG. 4 is a right isometric view of the embodiment shown in FIG. 1.

[0022] FIG. 5 is a schematic cross-sectional view through a portion of a light source having a light emitter and a reflector.

30 [0023] FIG. 6 is a top view of a programmable controller for use with a light therapy apparatus.

[0024] FIG. 7A is a partial cross-sectional view of a support arm of an embodiment of a light therapy apparatus showing the engagement between a track engaging ridge on a light source and a track formed in the support arm.

- 5 -

**[0025]** FIG. 7B is a partial cross-sectional view of a support arm of an embodiment of a light therapy apparatus showing the engagement between a track engaging ridge on a heat sink and a track formed in the support arm.

## 5 Description

**[0026]** Throughout the following description specific details are set forth in order to provide a more thorough understanding to persons skilled in the art. However, well known elements may not have been shown or described in detail to avoid unnecessarily obscuring the disclosure. Accordingly,  
10 the description and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

**[0027]** An embodiment of an orthodontic light therapy apparatus 20 is shown in FIGS. 1-4. Light therapy apparatus 20 has a frame 22 which is sized and shaped to engage with features of a person's face. In the exemplary  
15 embodiment illustrated in FIGS. 1-4, frame 22 is shaped to provide ear engaging portions 24, a nose engaging portion 26, and support arms 28. In some embodiments, frame 22 may be formed as an integral unit. In other embodiments, frame 22 may be formed from more than one separate piece of material, which are suitably joined to provide frame 22. In some  
20 embodiments, frame 22 may include more than one type of material; for example, support arms 28 may be made from a different material than other portions of frame 22.

**[0028]** Support arms 28 may be disposed so that they are adjacent to a person's jawbone when light therapy apparatus 20 is worn in a use  
25 configuration by a person. Portions 24 and 26 facilitate retention of light therapy apparatus 20 on the facial area of a person, while support arms 28 support a plurality of light sources 30 (also shown as light sources 30A-30H in some figures), as discussed below. Support arms 28 may also facilitate engagement of light therapy apparatus 20 on the facial region of a person,  
30 e.g. by providing a biasing force inwardly against a person's face. Other suitable configurations of frame 22 in addition to the illustrated embodiment could be used to secure light therapy apparatus 20 to a person's face and to support light sources 30 at the desired locations and with the desired orientations.

- 6 -

**[0029]** Frame 22 may be constructed from any suitable material; for example, lightweight plastic, aluminum, copper, copper clad materials (such as aluminum or steel), other suitable metal or plastic, tubular plastic, plastic composite embedded with metal particles, graphite, graphite-epoxy or the like. Frame 22 or portions of frame 22 may optionally include a resin covering and/or suitable padding to cushion a person's face. Frame 22 may be made from flexible material, and/or from material which is thermally conductive. If frame 22 is made from a thermally conductive material such as, for example, aluminum, frame 22 may enhance dissipation of heat from light source 30, described below.

**[0030]** Frame 22 may be made from a material which provides the frame with flexibility, which permits frame 22 to be conformed to the anatomical features of a particular person's face. A physician, dentist, orthodontist, therapist, technician or other professional may initially "fit" a particular light therapy apparatus 20 to a particular person by adjusting and conforming that particular light therapy apparatus 20 to the anatomical features of that particular person to provide an individualized fit. The material of which frame 22 is constructed may be sufficiently resilient to retain the individualized fit over the course of orthodontic therapy for that particular person, and yet sufficiently flexible to permit that particular light therapy apparatus 20 to be re-adjusted (e.g. in response to complaints of discomfort from a person) or adjusted to fit a different person.

**[0031]** Providing a flexible frame 22 may also facilitate light source 30 being pressed gently into the cheek of a person by support arms 28 (i.e. support arms 28 may bias light source 30 against the desired region of light administration on a person's jawbone). Pressure of light source 30 on the cheek of a person depresses the soft tissue, which may increase the effective transmission of light through the tissue. Optionally, regions of greater flexibility than the remainder of frame 22 may be provided between light sources 30 or at other suitable locations on frame 22, to allow frame 22 to be bent to provide a better fit around the facial area. Regions of greater flexibility may be provided, for example, by forming the region of greater flexibility from a thinner portion of material than the remainder of frame 22, by forming the region of greater flexibility from a more flexible material than

- 7 -

the remainder of frame 22, or by providing hinge-like members (e.g. a thin crease or other bend line set into the material of which frame 22 is constructed) within frame 22.

**[0032]** At least one light source 30 is secured to frame 22 in order to emit light towards a person when light therapy apparatus 20 is in the use position. Light source 30 is disposed extra-orally, i.e. outside of a person's oral cavity, when light therapy apparatus 20 is in the use position. The light provided by light source 30 is not necessarily visible light -- any desired wavelength may be used. For example, light emitted by light source 30 may include infrared light. Light source 30 may be any suitable light source, for example an array of light-emitting diodes (LEDs), or one or more than one laser, for example a vertical cavity surface emitting laser (VCSEL) or other suitable light emitter such as an Indium-Gallium-Aluminum-Phosphide (InGaAlP) laser, a Gallium-Arsenic Phosphide/Gallium Phosphide (GaAsP/GaP) laser, or a Gallium-Aluminum-Arsenide/Gallium-Aluminum-Arsenide (GaAlAs/GaAs) laser. A plurality of light emitters capable of emitting light at several different wavelengths may be used for light source 30.

**[0033]** Light source 30 may be of any convenient size and shape to flood a specified region of a person's maxillary and mandibular alveolar bone. For example, in some embodiments, light source 30 may have a height of approximately 9-10 mm along a vertical axis tangential to a person's face, and a width in the range of 15-18 mm along a horizontal axis tangential to a person's face, as measured when light therapy apparatus 20 is in the use configuration.

**[0034]** A plurality of light sources 30 may be disposed on frame 22 to deliver light of the desired wavelength substantially uniformly to desired regions of a person's maxillary and mandibular alveolar bone. Each individual light source 30 may be separately configured or separately controllable, to provide light of a specified wavelength and intensity to a specific region of a person's jawbone for a desired period. For example, in some instances, it may be desirable to apply light therapy only to certain regions of the person's maxillary and mandibular alveolar bone, if it is desired that teeth in other regions do not need to be moved (e.g. it may be

desired to move only the upper teeth of a person, or only the lower teeth, or to use certain teeth as an anchor when moving other teeth by applying no light therapy to the anchor teeth). It may also be desirable to provide light of different wavelengths to different regions of the person's maxillary and mandibular alveolar bone, if it is desired to differentially manipulate the movement of a person's teeth, as described below.

5 [0035] A person may position light therapy apparatus 20 herself to accurately and repeatedly illuminate a desired location in the person's dental and maxillofacial areas when light therapy apparatus 20 is in a use position. Consistent positioning of light therapy apparatus 20 during the course of a person's treatment may make therapy more effective and repeatable, and ease of use of light therapy apparatus 20 may facilitate patient compliance with a given treatment regimen.

10 [0036] In the embodiment illustrated in FIGS. 1-4, a plurality of light sources 30A, 30B, 30C, 30D, 30E, 30F, 30G, and 30H are disposed at symmetrical locations about frame 22. In other embodiments, a plurality of light sources 30 may be disposed asymmetrically about frame 22, the position of light sources 30 on frame 22 may be adjustable, and/or one or more than one light source 30 may be removable, to permit light therapy apparatus 20 to be configured to deliver light therapy to a specific region or regions of a person's maxillary and mandibular alveolar bone. For example, each light source 30 may be configured to illuminate the bone surrounding a specific number of teeth, for example two or three teeth, at a specific location.

20 [0037] In use, light is emitted from an inner surface 32 of light source 30 extra-orally towards a desired area. As used herein, the term "inner surface" refers to the surface of an element that is closest to the facial regions of a person when light therapy apparatus 20 is in the use position. Inner surface 32 may have rounded edges 33, as shown for example in FIGS. 7A and 7B, and may include a clear resin window covering the light emitters, to provide greater comfort for a person when light therapy apparatus 20 is in the use position.

25 [0038] Any suitable light emitting device may be used for light source 30. In some embodiments, light is emitted by arrays of discrete LEDs. The LEDs may be arranged in any of a wide variety of patterns. For example,

the LEDs may be arranged in staggered parallel rows to maximize the density of LEDs in the LED array. The LEDs may be arranged to achieve substantially uniform optical intensity over the light-emitting inner surface 32 of light source 30. In some embodiments, each array may comprise 5 to 20 LEDs or other light emitters. In some embodiments, each array may comprise 20-50 or more LEDs or other light emitters. In other embodiments, light from light source 30 may be emitted by one or more than one VCSEL. A plurality of VCSELs may be disposed in an array on light source 30. The VCSELs may be disposed in aligned or staggered parallel rows.

10 **[0039]** It is desirable that the average light intensity produced by light source 30 be at least about 10 mW/cm<sup>2</sup>. In some embodiments, light source 30 has an average intensity that is, or can be adjusted to be, in the range of about 20 mW/cm<sup>2</sup> to about 60 mW/cm<sup>2</sup>. In some embodiments, the output of light source 30 is pulsed. In such embodiments, the peak light intensity may  
15 be significantly higher than 50 mW/cm<sup>2</sup>.

**[0040]** In some embodiments, light emitters in light source 30 may be configured to deliver light having a wavelength in the range of about 585 nm to about 665 nm, about 815 nm to about 895 nm, about 640 nm to about 680 nm, or about 740 nm to about 780 nm, or any given wavelength or range of  
20 wavelengths within those ranges, such as, for example, about 625 nm or about 855 nm, or about 605 nm to about 645 nm, or about 835 nm to about 875 nm. In other embodiments, light emitters may be configured to deliver light having other wavelengths, as desired for a particular application.

**[0041]** Light source 30 may include optical elements such as lenses and  
25 reflectors to focus and direct light from light source 30 onto a target area. Such optical elements may be suitably encapsulated in plastic or similar material. FIG. 5 shows a portion of a light source 30. In the illustrated embodiment, a light emitter 38 (which may, for example, comprise a junction in a light-emitting diode or other light-emitting semiconductor  
30 device) is located adjacent to a reflective backing 40. A curved light-reflecting recess 42 is provided adjacent to light emitter 38. Light from light emitter 38 is reflected in recess 42 to form a beam. The beams from all light emitters of light source 30 combine to illuminate the target tissues. The area covered by the beam will depend upon the tissues which it is desired to

- 10 -

5 treat. In some embodiments, the beam of light emitted by light source 30 diverges to cover an area of tissue larger than the area of the light-emitting part of light source 30. In other embodiments the emitted light converges to provide increased light intensity at the location of the tissues that it is desired to treat. In some embodiments, the emitted light diverges in a beam having an included angle  $\theta$  in the range of about 45-60°.

10 **[0042]** Since LEDs and other light emitters give off heat when they are operated, it may be desirable to provide a suitable mechanism for dissipating the heat to prevent any parts of light therapy apparatus 20 that are proximate to a person's skin from getting too hot. In some embodiments, heat is dissipated by passive cooling, such as, for example, provision of appropriate heat sinks or permitting air to flow freely around light sources 30. Heat sinks 36 are an example of passive cooling. In some embodiments, light source 30 may include a forced air, liquid, or solid state cooling system. A cooling 15 system allows for administration of light therapy without the danger of potential burns to the person and allows for greater efficiency and control of the device. A cooling system may be installed on light therapy apparatus 20 in any suitable manner. In some embodiments, a cable recess (illustrated as 64A or 64B in FIGS. 7A and 7B) may be provided within light source 30 to accommodate aspects of a cooling system or cables that may be used with or 20 form part of light therapy apparatus 20.

25 **[0043]** In one embodiment that may use either passive or active cooling, or both, support arms 28 may be constructed from milled aluminum, and light source 30 may be constructed so as to be engageable with a track formed on the inner surface 34 of support arms 28, as shown for example in FIG. 7A. Light source 30 may be engageable with a track 60 formed in the inner surface 34 of support arms 28 via a track-engaging ridge 62A formed on light source 30. Track 60 and track-engaging ridge 62A may have any suitable complementary configuration and orientation to retain light source 30 30 against support arms 28 and oriented toward a wearer's face when light therapy apparatus 20 is in the use position. Light source 30 may be slideable within track 60, to facilitate the positioning of light source 30. Light source 30 may alternatively be coupled to support arms 28 in any other suitable manner, such as by a clip, clamp, adhesive, thermally conductive adhesive,

- 11 -

hook and loop fastener, or the like. In some embodiments, light source 30 may be integrally formed with support arms 28.

**[0044]** A heat sink 36 may interpose light source 30 and inner surface 34 of support arms 28. Heat sink 36 may, for example, be made of copper, aluminum, or other suitable thermally conductive material, to enhance dissipation of heat from light source 30. With reference to FIG. 7B, heat sink 36 may be engageable with track 60 formed in the inner surface 34 of support arms 28 via a track-engaging ridge 62B formed on heat sink 36. Track 60 and track-engaging ridge 62B may have any suitable complementary configuration and orientation to retain heat sink 36 against support arms 28, and to retain light source 30 oriented toward a wearer's face when light therapy apparatus 20 is in the use position. Heat sink 36 may alternatively be coupled to support arms 28 in any suitable manner, rather than via engagement with track 60 through optional track-engaging ridge 62B. For example, heat sink 36 may be coupled to light source 30 by a clip, clamp, adhesive, thermally conductive adhesive, hook and loop fastener, or the like. In some embodiments, heat sink 36 may be integrally formed with either or both of light source 30 or support arms 28.

**[0045]** A gas, liquid, or solid state cooling system may be provided on support arms 28 to maintain light source 30 at a suitable temperature, or passive cooling means may be employed as previously described. In some embodiments, the temperature of the inner surface 32 of light source 30 may be maintained below a temperature of about 41°C. A cable recess, illustrated for example as 64A or 64B (FIGS. 7A and 7B) may be provided in light source 30 to accommodate cables for carrying electricity to light source 30 and/or components of a gas or liquid cooling system, or the like. An optional sensor or a controller 50 as described below may be provided, to automatically switch off any light source if the temperature of inner surface 32 or some other designated portion of that particular light source 30 exceeds a predetermined value.

**[0046]** In some embodiments, light therapy apparatus 20 is disposed and supported exclusively or substantially external to a mouth of a person. A light therapy apparatus which is supported exclusively or substantially external to a mouth of a person may facilitate the use of that light therapy

- 12 -

apparatus with a wide variety of intra-oral orthodontic devices. In other embodiments, a portion of light therapy apparatus 20 may be disposed within a mouth of a person, to assist in securing and/or positioning light therapy apparatus 20 on a person's head. For example, bite wings or an intra-oral tray which is supported in position by having a person hold the intra-oral tray between her upper and lower teeth may be coupled to light therapy apparatus 20 to assist in retaining or supporting the apparatus. An example of a suitable intra-oral tray is described in PCT publication numbers WO 2009/000075 and WO 2006/087633, both of which are incorporated by reference herein.

**[0047]** To calibrate light therapy apparatus 20, a sensor to measure reflectance (not shown) may be provided at a location that will be adjacent the skin of a person when light therapy apparatus 20 is in the use position. The sensor may measure the reflectance of light from the skin of the person, and if the value measured is outside a predetermined range (e.g. because light therapy apparatus 20 has been displaced from a person's head), the sensor may automatically pause a treatment and/or the emission of light from light source 30. Pausing treatment and/or the emission of light if light therapy apparatus 20 is displaced from a person's head may minimize the risk of accidental injury, e.g. due to exposure of a person's eyes to light from light source 30.

**[0048]** To be most effective, the light from light source 30 at the tissues to be treated should have at least a threshold intensity. Light source 30 may be operated in a pulsed mode to facilitate cooling of light source 30 while ensuring that when light source 30 is emitting light, the intensity of emitted light at the tissues to be treated is sufficient to be effective. In some embodiments, the duty cycle of light source 30 is 1:1 or less, in some embodiments 1:2 or less (i.e. for each interval in which light source 30 is on, light source 30 is off for two equal intervals). In some embodiments, the duty cycle of light source 30 may be 1:10. Peak intensity may be increased, e.g. in embodiments in which light source 30 is operated at a low duty cycle, to provide light of the desired intensity. The pulsing of light source 30 may be performed fast enough that light source 30 does not visibly flicker (e.g. at 25 Hz or more) although this is not mandatory.

- 13 -

**[0049]** The light emitted by light source 30 may be substantially monochrome in some embodiments, although this is not mandatory. Providing light emitters that emit at multiple wavelengths allows for irradiation over multiple wavelengths for greater biological activity and greater selectivity and precision in administration. The light may comprise incoherent light, although this is not mandatory. The light may be delivered continuously or pulsed at suitable frequencies and duty cycles.

**[0050]** In some embodiments in which the emitted light includes infrared light, the emitted light also includes bright visible light. The bright visible light deters users from looking into light source 30 when it is operating, provides a perceptible indication that the apparatus is operating, and may be useful in properly positioning the light therapy device 20. The visible light may be, but is not necessarily, in a wavelength range that is beneficial for light therapy. In some embodiments, the ratio of the intensities of the visible and infrared components of the light is 1 part or less visible light to 5 parts or more infrared light.

**[0051]** FIG. 6 illustrates a programmable controller 50 of a type that may be used to control the operation of light therapy apparatus 20. Although controller 50 is described in this exemplary embodiment as being programmable, it is not necessary that controller 50 be programmable. For example, a controller may have controls that allow various parameters to be set, such as light wavelength, light intensity, or the like, and may appropriately activate light sources 30 in response to an appropriate signal. Each of the light sources, e.g. light sources 30A-30H shown in FIG. 2, may be regulated independently by one or more controllers 50. A physician, dentist, orthodontist, therapist, technician or other professional may set those controls or program controller 50 so that an appropriate treatment is delivered when a person initiates delivery of the treatment.

**[0052]** Programmable controller 50 may be a separate, remote unit or may be directly connected to or integrated with a light source 30. A cable 52 may be provided to connect light therapy apparatus 20 to programmable controller 50, a source of electricity for light source 30, a suitable heating or cooling system, or the like. In some embodiments, controller 50 may comprise a microprocessor, data store, power supply, clock and associated

- 14 -

electronic circuitry. Control parameters are stored in the data store.

Programmable controller 50 operates light source 30 according to the

parameters in the data store. The parameters may specify one or more of:

treatment duration; wavelength of light emitted by light emitters 38; light

5 intensity during the treatment; whether light emitters 38 operate continuously or are pulsed; if light emitters 38 are pulsed, the rate at which light emitters 38 are pulsed; if light emitters 38 are pulsed, the duty cycle at which light emitters 38 are pulsed; etc.

**[0053]** If light therapy apparatus 20 has sets of light emitters 38 having  
10 different characteristics (e.g. sets of LEDs that emit light at different wavelengths or sets of light sources 30 that illuminate target tissues in different locations) then separate control parameters may be provided for different sets of the light emitters 38 and/or light sources 30. In some embodiments, different sets of parameters are specified for different segments  
15 (intervals) of a light treatment. For example, light therapy treatments may be defined for a set of intervals each lasting from a few seconds to a few hundred seconds or a fraction of an hour. Different parameters may be specified for each of the intervals. The intervals are not necessarily equal in length.

20 **[0054]** In some embodiments, different sets of parameters may be specified for different areas of light therapy apparatus 20. In some cases, some light sources 30 of light therapy apparatus 20 may be turned off because the treatment plan for a person does not require light to be delivered at locations corresponding to those parts of the light therapy apparatus 20. For  
25 example, with reference to FIG. 2, programmable controller 50 may be programmed such that only light sources 30A, 30B, 30C and 30D are activated for a particular treatment regime in which it is desired that light therapy be applied only to a person's upper teeth. Alternatively, programmable controller 50 may be programmed such that only light sources  
30 30A, 30D, 30E and 30H are activated for a particular treatment regime in which it is desired that light therapy be applied only to a person's molars. Various other combinations and permutations of the activation of various light sources disposed about light therapy apparatus 20 in any suitable configuration may be devised and implemented, depending on the desired

- 15 -

application. In some embodiments, light therapy apparatus 20 is configured (i.e. light sources 30 are positioned and oriented) so as to provide substantially uniform illumination of substantially the entire maxillary and mandibular alveolar bone and teeth of a person.

5 **[0055]** A physician, dentist, orthodontist, therapist or other professional may program a person's treatment regimen into programmable controller 50. This may be done, for example, with the aid of suitable software running on a computer that is in data communication with programmable controller 50 or by way of a suitable user interface built into  
10 programmable controller 50.

**[0056]** Programmable controller 50 may have one or more pre-set programs built in. As an alternative to, or as an aid to programming controller 50, the physician, dentist, orthodontist, therapist or other professional may select a pre-set program that is appropriate for controlling  
15 light therapy apparatus 20 to deliver light to a person.

**[0057]** Programmable controller 50 may maintain a log of treatments that have been delivered. For example, controller 50 may log the date and time that each treatment was initiated, the duration of the treatment, and whether or not the treatment was completed. This log may be subsequently  
20 reviewed by a dentist, physician, orthodontist or the like to evaluate whether or not the person has complied with a prescribed treatment regimen. The log may track the times and durations of light therapy treatments delivered by light therapy apparatus 20 and may also track other features such as operating temperatures, operational status and the like.

25 **[0058]** Programmable controller 50 has a button or other suitable user patient interface that allows a patient to initiate a treatment according to previously-set parameters in the data store. The patient interface is preferably very simple such that minimal instruction is required to explain to a patient how to use light therapy apparatus 20. Programmable controller 50 may  
30 include an audible or visual indicator that generates a signal to remind a patient that it is time for a treatment (or that a scheduled treatment is overdue).

- 16 -

**[0059]** A patient may use light therapy apparatus 20 at home or in another location by operating programmable controller 50 to initiate delivery of a treatment.

**[0060]** Programmable controller 50 may comprise circuitry that  
5 monitors temperature at one or more locations in light source 30. The circuitry may monitor a signal modulated by a temperature sensor in light source 30. In other embodiments, programmable controller 50 may monitor e.g. the current and voltage driving LEDs in light source 30. The current/voltage relationship is temperature-dependent. Thus, by monitoring  
10 the current/voltage relationship programmable controller 50 can determine whether the LED is at an undesirably high temperature. Programmable controller 50 may shut off or reduce current to any particular light source (e.g. one or more of light sources 30A-30H) when it detects that the temperature of that light source is undesirably high (or is trending towards  
15 being undesirably high). If light therapy apparatus 20 is provided with a cooling apparatus, controller 50 may increase the operation of the cooling apparatus when it detects that the temperature of light source 30 is above a desired level.

**[0061]** In use, a physician, dentist, orthodontist, therapist or other  
20 professional may program a person's prescribed treatment regimen into a programmable controller 50 (see FIG. 6, for example). Programmable controller 50 controls parameters of a light therapy treatment to be delivered by light therapy apparatus 20. For example, controller 50 may control the duration of the treatment, wavelength of light delivered, light intensity, pulse  
25 frequency, etc. Programmable controller 50 runs a patient's prescribed treatment regimen causing the at least one light source 30 to emit pulsed or continuous light of specified wavelengths according to the prescribed parameters onto the treatment area of a person's maxillary and mandibular alveolar bone. Light therapy device 20 can provide effective, stabilized  
30 repeatable, accurate, programmable, and consistent light therapy for a desired treatment to specifically deliver light of a desired wavelength to a particular treatment region at a substantially uniform intensity. Scattering of light as it enters a person's soft tissues may also cause the beam of light to diverge, resulting in uniform illumination of the person's soft and hard tissue.

- 17 -

**[0062]** Light therapy apparatus 20 or other suitable light therapy device may be used in the orthodontic treatment of a person, in conjunction with a conventional orthodontic appliance. Conventional orthodontic appliances may include, for example, fixed active appliances such as pin and tube  
5 appliances, ribbon arch appliances, Begg lightwire appliances, edgewise appliances, pre-adjusted edgewise appliances, self-ligating edgewise appliances, bi-helix, tri-helix, quad-helix, rapid maxillary expansion appliance (RPE); removable active appliances such as expansion and labial  
10 segment alignment appliance INVISALIGN™; functional appliances such as herbst, bionator, frankel, biobloc, activator; orthodontic headgear including reverse headgear and conventional headgear; and other types of orthodontic apparatus.

**[0063]** To aid in regulating or accelerating the movement of teeth during orthodontic treatment with a conventional orthodontic appliance,  
15 infrared light having wavelengths in the range of about 585 nm to about 665 nm, about 815 nm to about 895 nm, about 640 nm to about 680 nm, or about 740 nm to about 780 nm may be applied extra-orally to appropriate regions of a person's maxillary and mandibular alveolar bone. In some embodiments, the wavelengths may be between about 605 nm to about 645 nm, or between  
20 about 835 nm to about 875 nm. In some embodiments, the wavelengths may be between about 615 nm to about 635 nm, or between about 845 nm to about 865 nm. In some embodiments, the wavelengths may be about 625 nm or about 855 nm. As discussed below, both the speed of tooth movement through the bone and the characteristics of that movement (i.e. "bodily"  
25 movement wherein the tooth is generally perpendicular to the bone, versus "tipped" movement, wherein the crown or coronal region of the tooth advances more quickly than the root or apical region of the tooth) may be regulated by application of the appropriate light therapy. Bone regeneration may also be enhanced by light therapy during or after orthodontic treatment.

**[0064]** As discussed above, light sources 30 on various regions of light  
30 therapy apparatus 20 may be modulated individually, to expose individual sections of a person's maxillary and mandibular alveolar bone to a desired energy density. For example, applying light selectively may enable an increased anchorage effect (by reason of lower tooth mobility) of teeth which

- 18 -

are not exposed to any light, which may thereby permit for more precise movement of teeth to which light is applied using light therapy apparatus 20.

**[0065]** Based on studies conducted in an accepted rat model for measuring orthodontic treatments (discussed with reference to the Examples below), treatment of the alveolus and teeth of a person with infrared light having a wavelength in the range of about 815 nm to about 895 nm, including about 835 nm to about 875 nm, and about 855 nm, may be used to significantly increase the rate of movement of teeth without increasing the tipping motion of teeth beyond that experienced by orthodontic patients who are not provided with light therapy.

**[0066]** Treatment of the alveolus and teeth of a person with infrared light having a wavelength in the range of about 585 nm to about 665 nm, including about 605 nm to about 645 nm, and about 625 nm, may likewise be used to increase the rate of movement of teeth. While treatment with light of this shorter wavelength may not increase the speed of tooth movement as significantly as longer wavelengths of infrared light, more “bodily” movement of teeth through the alveolus was found in an experimental model at this wavelength, as summarized below. Thus, light having a wavelength in the range of about 605 nm to about 645 nm, including about 625 nm, may be used to facilitate the bodily movement of teeth in orthodontic treatment and provide improved bone regeneration, while light having a wavelength in the range of about 835 to about 875 nm, including about 855 nm, may be used to accelerate the movement of teeth for which tipping movement is desirable or acceptable, and may also improve bone regeneration, although not as significantly as light therapy using a wavelength in the range of about 625 nm.

**[0067]** Additionally, treatment with light having a wavelength in the range of about 605 nm to about 645 nm, including about 625 nm, may also increase the quality and degree of bone remodelling. Increasing the quality and degree of bone remodelling may aid in increasing the retention of teeth in their final position, resulting in a decreased potential for teeth to move back toward their initial positions. Thus, following orthodontic treatment, which may be performed in conjunction with light therapy at a desired wavelength, for example infrared light of longer wavelengths (e.g. in the range of 815 nm

- 19 -

to 895 nm) treatment with light having a wavelength in the range of about 585 nm to about 665 nm, or about 605 nm to about 645 nm, or about 615 nm to about 635 nm, or about 625 nm, may be used to stabilize teeth following orthodontic treatment. Optionally, a retainer device or passive orthodontic appliance may be used in conjunction with light therapy at these wavelengths to stabilize tooth movement. For example, suitable devices include removable retainers such as a Hawley retainer or a vacuum formed retainer, or fixed retainers such as a bonded lingual retainer. This treatment may assist in maintaining tooth position following orthodontic treatment, for example by stimulating bone regeneration. Treatment with light having a wavelength in the range of about 815 nm to about 895 nm, or about 835 nm to about 875 nm, or about 845 nm to about 865 nm, or about 855 nm, may also be used to stabilize tooth movement following orthodontic treatment, although bone regeneration may be enhanced to a somewhat lesser extent than with wavelengths in the range of about 585 nm to about 665 nm.

**[0068]** Accordingly, by applying infrared light having an appropriate wavelength, the speed, quality and type of tooth movement, e.g. bodily versus tipped, may be modulated, and tooth movement may be accelerated or stabilized. Bone regeneration may be improved. In some embodiments, the light therapy may be applied to substantially the entirety of a person's maxillary and mandibular bone. Alternatively, using a light therapy apparatus or other suitable device, light of the appropriate wavelength may be applied to different selected regions of a person's maxillary and mandibular alveolar bone in order to produce the desired movement of teeth (e.g. anchor (no movement), bodily, or tipped) in each region of a person's mouth. For example, regions in which it is desired that the teeth not be moved, or that the teeth serve as an anchor to facilitate movement of teeth in other selected regions of a person's jaw, may receive no light therapy. Regions in which it is desired that the teeth be moved bodily may be exposed to light having a wavelength in the range of about 585 nm to about 665 nm, in the range of about 605 nm to about 645 nm, about 615 nm to about 635 nm, or about 625 nm. Regions in which it is desired to accelerate tooth movement but permit greater tipping of the teeth may be exposed to light having a wavelength in the range of about 815 nm to about 895 nm, about

- 20 -

835 nm to about 875 nm, about 845 nm to about 865 nm, or about 855 nm. Tooth movement may be selectively regulated by applying an effective dosage of light having one wavelength to selected regions of a person's maxillary and mandibular bone, and by applying an effective dosage of light having a  
5 different wavelength to different selected regions of the bone.

**[0069]** An effective dosage of light may be in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>. The effective dosage of light may be administered repetitively. In some embodiments, the effective dosage may be between 30 J/cm<sup>2</sup> to 100 J/cm<sup>2</sup>. The dosage of light may be increased, for example, by using a light  
10 source that produces light having a higher average intensity, or by increasing the duration of administration of light.

**[0070]** The duration over which the effective repetitive dosage is administered may be in the range of 10 to 40 minutes. The effective repetitive dosage may be administered with any desired frequency, e.g. daily  
15 or every second day, weekly or biweekly. Light therapy may be administered throughout the time period that a person is undergoing orthodontic treatment, and/or following treatment to stabilize tooth movement. It may be desirable to apply light therapy with greater frequency, e.g. daily or every second day, while a person is undergoing orthodontic  
20 treatment. Where light therapy is being used to stabilize tooth movement, treatments of reduced frequency, e.g. weekly or biweekly, may be used to minimize inconvenience to persons. The light may be applied extra-orally to a person's maxillary and mandibular alveolar bone through the person's cheek using a light therapy apparatus 20, or by the application of light to a  
25 person's alveolar bone by any other suitable method, such as for example manually retaining a light source providing light of the desired wavelength over the appropriate treatment region(s) of a person.

**[0071]** Embodiments of the invention may also have application in other areas. For example, extra-oral application of light emitting arrays on  
30 the condylar portion of the mandible can increase the growth of the mandible in orthopedic expansion and grow treatments. Other conditions which may be treated with embodiments of devices according to the invention include: jaw osteonecrosis, other jaw bone disorders, periodontitis, malocclusion and other conditions treated by orthodontics, stimulation and acceleration of

healing after oral surgery or periodontal surgery, stimulation of the healing of wounds at the locations of bone grafts, healing and acceleration of osseo-integration of endosseous dental implants; and, the like.

## 5 Examples

[0072] The invention is further described with reference to the following specific examples, which are not meant to limit the invention, but rather to further illustrate it.

### 10 **1.0 EXPERIMENTS IN A RAT MODEL OF ORTHODONTIC TOOTH MOVEMENT**

#### **1.1 Animal Model**

[0073] Experiments were performed on nineteen healthy adult CRL-CD male rats according to an accepted model for orthodontic tooth movement  
15 (see e.g. Ren Y, Maltha JC and Kuijpers-Jagtman AM, “The rat as a model for orthodontic tooth movement—a critical review and a proposed solution.” *Eur. J. Orthodontics*, 2004, 26(5): 483-90; and Sebaoun JD, Kantarci A, Turner JW, Carvalho RS, Van Dyke TE, Ferguson DJ, “Modeling of trabecular bone and lamina dura following selective alveolar decortication in  
20 rats.” *J. Periodontol.*, 2008, 79(9):1679-88).

[0074] One group received only orthodontic treatment (“TM”); one group received light therapy from an LED light source at a red wavelength of 625 nm at a dose of 10 J/cm<sup>2</sup> (“LED Short”) another group at 625 nm at a dose of 30 J/cm<sup>2</sup> (“LED Long”). A fourth experimental group received light  
25 therapy from a laser light source at a near infrared (IR) wavelength of 855 nm at a dose of 10 J/cm<sup>2</sup> (“Laser Short” or “IR Short”), and a fifth experimental group at 855 nm at a dose of 30 J/cm<sup>2</sup> (“Laser Long” or “IR Long”). In all cases, the energy density of the applied light was 30 mW/cm<sup>2</sup>, for either 333 seconds (short) or 1000 seconds (long) using an OsseoPulse™  
30 device (Biolux Research Ltd.) to provide the desired dosage (i.e. 10 J/cm<sup>2</sup> or 30 J/cm<sup>2</sup>). Light was applied transcutaneously (i.e. extra-orally through the skin). Animals were treated for 21 days prior to analysis.

[0075] In groups receiving orthodontic treatment, an orthodontic appliance was applied to move the left maxillary first molar to the mesial. A

- 22 -

stainless steel ligation wire was used to ligate a 25 gramm Sentalloy® coil spring, activated for 10 mm, to the left maxillary molar and the incisors.

### *1.2 Radiographic Analysis*

- 5 [0076] To measure the amount of tooth movement, two-dimensional radiographic images were taken on dissected maxillae of the animals by using Faxitron® imaging and the mesiodistal distance between the most mesial aspect of the second to the most distal aspect of the first molar was measured in millimetres on a line parallel to a line following the midpalatal suture.
- 10 [0077] Micro-CT images were obtained to show the bone response. All measurements were performed for two regions of interest: the interradicular area of the first molar (ROI-1) and the area between the distal roots of the first molar and the mesial roots of the second molar (ROI-2). Coronally the region of interest ended at the last level, which showed the five roots of the
- 15 first molar, separated. The apical limit was the last level all five roots could be identified. The bone quantity was described by the bone volume (BV, mm<sup>3</sup>), the ratio of bone volume to total volume (BV/TV), the quality of the bone by the bone mineral density (BMD, mg hydroxyapatite (HA)/cm<sup>3</sup>), and the bone mineral capacity (BMC, mg HA).

20

### *1.3 Histopathology*

- [0078] Samples through the first, second, and third molar roots were obtained, and slides at three different vertical levels of the roots (apical, middle and coronal) were stained with hematoxylin & eosin (H&E). Two
- 25 areas were morphometrically assessed, the area between the first molar roots including the roots (ROI-1) and the area between the distal roots of the first molar and the mesial roots of the second molar (ROI-2).

- [0079] Histomorphometric analysis was performed to analyze the amount of trabecular bone and the ratio to the total interradicular area after
- 30 orthodontic treatment alone or in combination with light therapy compared to baseline levels for three different vertical levels: coronal, middle and apical. ROI-1 was assessed via a pentagon shaped grid on images of the first molars, each angle formed by the centre of the first five molar roots. ROI-2 was assessed as a square shaped grid on images of the area between the first and

second molar roots with angles in the centre of the two distal roots of the first and two mesial roots of the second molar. Within both grids, the total amount of bone and periodontal ligament was recorded in square millimeters and calculated as a percentage of the total area.

5 **[0080]** Catabolic activity in the alveolar bone was assessed and slides at three different levels were stained with tartrate resistant acid phosphatase (TRAP). The number of TRAP-stained osteoclasts and pre-osteoclasts in images of the first and third molars were recorded within the captured  
 10 interradicular area of 1.17mm<sup>2</sup> to measure the catabolic activity within the periodontal ligament and trabecular bone. Cell counts were performed on each of the three different levels per specimen and per molar and then averaged. Measurements were also performed at the control side (i.e. the contralateral untreated side of the rat maxilla).

15 **2.0 RESULTS**

**2.1 ROI-2**

*2.1.1 Two-dimensional Measurements of Gained Space in Faxitron® Images*

**[0081]** Two dimensional measurements at the coronal level of the teeth demonstrated significantly ( $p < 0.05$ ) greater mesial movement of the first  
 20 molar in the LED Long, Laser Short and Laser Long groups (1.46 mm, 1.88 mm and 1.50 mm, respectively) as compared to the TM group receiving no light therapy (0.51 mm) (see Table 1). LED Short showed increased but not significantly different results (1.17 mm) compared to the TM group. Thus,  
 25 light therapy at 855 nm appears to provide greater acceleration of tooth movement than light therapy at 625 nm.

**Table 1. Two-dimensional measurements of gained space in Faxitron® images for ROI-2.**

		Average Tooth Movement (mm)	Standard Deviation
30	LED Short	1.17	0.70
	LED Long	1.46*	0.54
	IR Short	1.88*	1.14
	IR Long	1.50*	1.74
	TM	0.51	0.05

35 \*  $p < 0.05$  compared to TM

- 24 -

### 2.1.2 Trabecular Bone Surface

**[0082]** Histopathological analysis of the slides stained with hematoxylin-eosin showed significantly ( $p < 0.05$ ) less trabecular bone surface compared to baseline in the LED Long, Laser Short, Laser Long ( $0.01-0.11$  mm<sup>2</sup>) as well as the TM group ( $0.17 \text{ mm}^2 \pm 0.16$ ). LED Short ( $0.32$  mm<sup>2</sup>  $\pm 0.30$ ) was the only group that showed no significantly reduced trabecular bone surface compared to baseline ( $0.55 \text{ mm}^2 \pm 0.07$ ). Additionally in the LED Short group, the trabecular bone was still present on the palatal side of ROI-2, similar to the TM group, while the other groups receiving light therapy showed bone loss within the whole buccopalatal aspect of the alveolar crest.

**[0083]** As to trabecular bone surface in the vertical dimension, the coronal surface in the LED Short (22.10%) group showed significantly more bone compared to TM (1.03%) and equivalent values for the middle and apical levels, thus demonstrating more bodily tooth movement as compared with the tipping observed for the TM group (see Table 2). The coronal (22.10%) and middle level (24.34%) of the LED Short group had also significantly more trabecular bone surface compared to the Laser groups (0.00% and 7.82% coronal; 0.93% and 9.81% middle for Laser Short and Laser Long, respectively).

**Table 2. Trabecular bone surface in the vertical dimension for ROI-2.**

			% of Trabecular Bone	Std. Dev.
25	LEDshort	Coronal	22.10**a	22.81
		Middle	24.34#a	20.52
		Apical	28.76	21.99
30	LEDlong	Coronal	6.91**	11.97
		Middle	9.78**	14.59
		Apical	13.25**	12.79
35	IRshort	Coronal	0.00**	0
		Middle	0.93**	1.62
		Apical	4.04**	3.48
40	IRlong	Coronal	7.82**	13.54
		Middle	9.81**	16.99
		Apical	12.80**	18.04
45	Baseline	Coronal	36.46	5.05
		Middle	42.50	2.79
		Apical	52.56	9.76
50	TM	Coronal	1.03**	1.79
		Middle	5.16**	7.96
		Apical	29.03	29.86

- \* p<0.05 compared to TM
- \*\* p<0.05 compared to baseline
- # p<0.05 compared to IR Short
- <sup>a</sup> p<0.05 compared to IR Long

5

**2.1.3 Bone Quality**

[0084] With reference to Table 3, in order to look at the quantity and quality of trabecular bone, micro-CT results were evaluated. Distal of the mesialized first molar the micro-CT evaluation of the quantity of bone showed the highest bone volume (BV) for the LED Short group (0.60 mm<sup>3</sup>), which was significantly higher than Laser Short (0.13 mm<sup>3</sup>) and Laser Long groups (0.20 mm<sup>3</sup>). Significantly higher values for the bone mineral content (BMC) were also found in the LED Short group (0.52 mg HA) compared to the Laser groups (0.11 and 0.18 mm HA for Laser Short and Laser Long, respectively). The Laser groups showed less BV and BMC compared to LED Short and LED Long and TM groups, demonstrating a lower quality of movement in the Laser groups compared to all others. BMD values were not significantly different between groups.

20 **Table 3. Micro-CT results for ROI-2, including bone volume (BV, mm<sup>3</sup>), bone volume to total volume (BV/TV), bone mineral density (BMD, mg hydroxyapatite (HA)/cm<sup>3</sup>), and bone mineral capacity (BMC, mg HA).**

		BV		BV/TV		BMD		BMC	
		(mm <sup>3</sup> )				(mg HA/cm <sup>3</sup> )		(mg HA)	
		Avg.	Std. Dev.	Avg.	Std. Dev.	Avg.	Std. Dev.	Avg.	Std. Dev.
25	LEDshort	0.60* <sup>#</sup>	0.42	0.46*	0.07	880.72	69.84	0.52* <sup>#</sup>	0.36
	LEDlong	0.35	0.18	0.42	0.14	886.32	15.86	0.31	0.16
	IRshort	0.13	0.02	0.25	0.05	835.42	51.85	0.11	0.02
	IRlong	0.20	0.05	0.38	0.15	895.88	24.30	0.18	0.05
30	TM	0.45	0.08	0.45*	0.05	910.23	10.66	0.41	0.08

- \* p<0.05 compared to IR Short
- <sup>#</sup> p<0.05 compared to IR Long

**2.2 ROI-1**

**2.2.1 Trabecular Bone Surface**

35 [0085] The histomorphometric evaluation of the trabecular bone surface within the roots of the first molar showed significantly higher values for the amount of bone in all groups receiving extra-oral light therapy (60.67%-71.45%) as compared to tooth movement alone (TM) (30.71%).

The TM group showed less bone in the coronal aspect as compared with the apical area (Table 4). For the apical level all four groups receiving light therapy had significantly better bone values (71.36%, 62.84%, 37.58% and 35.87% for LED Short, LED Long, Laser Short, and Laser Long, respectively) as compared to TM (39.95%). For the middle and coronal level all groups showed significantly increased bone compared to TM, and only Laser Short showed slightly lower values. Thus, bone regeneration within the center of the first molar roots appears to be significantly improved by all types of light therapy as compared to orthodontic treatment alone.

10

**Table 4. Histomorphometric evaluation of trabecular bone surface within ROI-1.**

			% of Trabecular Bone	Std. Dev.
15	LEDshort	Coronal	71.36*#	12.25
		Middle	69.48	11.71
		Apical	73.56*	9.14
20	LEDlong	Coronal	62.84	12.22
		Middle	65.62	9.39
		Apical	69.37	5.12
25	IRshort	Coronal	37.58	31.65
		Middle	42.63	62.21
		Apical	62.89*	7.52
30	IRlong	Coronal	35.87*	30.16
		Middle	50.17	38.88
		Apical	68.22*	12.68
35	TM	Coronal	17.34	13.02
		Middle	34.83	20.68
		Apical	39.95	15.03

\* p<0.05 compared to TM

# p<0.05 compared to LED Long

*2.2.2 Bone quality*

**[0086]** With reference to Table 5, results of a micro-CT evaluation of ROI-1 are shown. The ratio of the bone volume to the total volume of the measured area (BV/TV) showed no significant difference between all groups and compared to baseline. With respect to bone mineral density (BMD), Laser Short (833.77mg HA/cm<sup>3</sup>) showed the lowest bone density and was significantly below baseline (874.05 mg HA/cm<sup>3</sup> ± 29.23).

40

**Table 5. Micro-CT results for ROI-2, including bone volume (BV, mm<sup>3</sup>), bone volume to total volume (BV/TV), bone mineral density (BMD, mg hydroxyapatite (HA)/cm<sup>3</sup>), and bone mineral capacity (BMC, mg HA).**

	BV		BV/TV		BMD		BMC		
	(mm <sup>3</sup> )				(mg HA/cm <sup>3</sup> )		(mg HA)		
	Avg.	Std. Dev.	Avg.	Std. Dev.	Avg.	Std. Dev.	Avg.	Std. Dev.	
5									
	LEDshort	1.04	0.24	0.67	0.09	864.54	29.99	0.90	0.18
	LEDlong	0.69	0.30	0.63	0.24	867.53	28.72	0.60	0.28
	IRshort	1.13	0.08	0.60	0.03	833.77 <sup>#</sup>	4.86	0.95	0.07
	IRlong	1.24 <sup>*</sup>	0.27	0.79	0.03	853.29	21.86	1.06 <sup>*</sup>	0.25
10	Baseline	1.20 <sup>*</sup>	0.26	0.73	0.06	874.05	29.23	1.05 <sup>*</sup>	0.25
	TM	1.18	0.45	0.67	0.15	855.68	9.29	1.01	0.38

\* p<0.05 compared to LED Long

# p<0.05 compared to baseline

15 **2.2.3 Osteoclastic Activity**

**[0087]** To evaluate catabolic activity, TRAP+osteoclasts and preosteoclasts were counted. When the osteoclasts were counted within the roots of the first molar, significantly higher osteoclast counts were found in all groups with tooth movement as compared to baseline (5.17

20 osteoclasts/1.17 mm<sup>2</sup>) (see Table 6). Within the orthodontic treatment groups, there was no significant difference for all five groups, regardless of the presence or type of light therapy.

**Table 6. Results of assays for osteoclastic activity within roots of first molar.**

	Average # of Osteoclasts per 1.17mm <sup>2</sup>	Std. Dev.
30		
	LEDshort	39.33 <sup>*</sup>
	LEDlong	34.56 <sup>*</sup>
	IRshort	33.44 <sup>*</sup>
	IRlong	45.78 <sup>*</sup>
	Baseline	5.17
	TM	33.33 <sup>*</sup>

\* p<0.05 compared to baseline

35 **2.2.4 Distant Effects**

**[0088]** To evaluate distant effects of light therapy, the osteoclastic activity within the roots of the third molar was evaluated. The tooth movement (TM) group showed increased osteoclast counts (26.22

osteoclasts/1.17 mm<sup>2</sup>) compared to baseline levels (15.25 osteoclasts/1.17 mm<sup>2</sup>) in the distant area of the third molar. Within the groups receiving light therapy, the two groups receiving the higher dose of light therapy showed increased osteoclast counts as well. The LED Short group (11.33  
 5 osteoclasts/1.17 mm<sup>2</sup>) showed significantly less osteoclastic activity in the roots of the third molar than the LED Long, Laser Long and TM group (33.56, 25.00 and 26.22 osteoclasts/1.17 mm<sup>2</sup>, respectively) (see Table 7).

10 **Table 7. Results of assays for osteoclastic activity within roots of third molar.**

	Average # of Osteoclasts per 1.17mm <sup>2</sup>	Std. Dev.
LEDshort	11.33	2.00
LEDlong	33.56*	8.00
IRshort	18.00	8.41
15 IRLong	25.00*	6.17
Baseline	15.25	4.39
TM	26.22*	9.32

\* p<0.05 compared to LED Short

20 **2.2.5 Penetration of Light**

[0089] With reference to Table 8, the trabecular bone surface and the osteoclastic activity on the control side were evaluated to examine any deep effects from light therapy. Within the roots of the first molar on the control side the trabecular bone surface showed comparable values within all groups and compared to baseline. Similar results were found for osteoclastic activity.  
 25

**Table 8. Trabecular bone surface and osteoclastic activity on the first molar on the control side, based on staining with H&E and TRAP.**

	H&E		TRAP	
	Average % of Trabecular Bone	Std. Dev.	Average # of Osteoclasts per 1.17mm <sup>2</sup>	Std. Dev.
LEDshort	64.81	7.02	6.89	1.84
LEDlong	63.13	5.77	9.67	5.93
IRshort	57.10	5.86	5.00	2.08
IRlong	63.89	3.93	5.00	2.85
35 Baseline	65.03	2.00	4.67	1.52
TM	45.59	9.24	14.56	8.18

### **3.0 ANALYSIS OF RESULTS**

**[0090]** The lowest rate of bone resorption and the better bone regeneration was observed in the LED Short group. However, the acceleration in tooth movement, while greater than in the absence of light therapy, was not as significant as in the Laser groups. Thus, light therapy applied at 625 nm has a high potential for improving bone regeneration, but at a slower rate of accelerated tooth movement than is achievable using near infrared light therapy at 855 nm. However, light therapy at 625 nm can still accelerate tooth movement as compared with traditional orthodontic therapy without light therapy.

**[0091]** The differential effects of light therapy at 625 nm versus 855 nm may be advantageously used, for example, in sub-optimal periodontal conditions. In such circumstances, the conservation of the reduced bone with less resorptive activity distant from the site of tooth movement could be of benefit.

**[0092]** Moreover, light therapy does not appear to cause negative side effects. All treatment groups receiving light therapy appeared to show a regional acceleration of metabolic activity, without deep effects due to the light therapy.

**[0093]** While a number of exemplary aspects and embodiments have been discussed above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.

- 30 -

WHAT IS CLAIMED IS:

1. A method for regulating tooth movement during orthodontic treatment of a person, comprising the steps of:
  - 5 applying a conventional orthodontic appliance to the person; and
  - 5 applying an effective repetitive dosage of light extra-orally to a selected region of the person's maxillary and mandibular alveolar bone.
2. A method according to claim 1, wherein the selected region comprises substantially the entirety of the person's maxillary and mandibular  
10 bone.
3. A method according to claim 1, wherein the effective repetitive dosage of light is in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>.
- 15 4. A method according to claim 3, wherein the effective repetitive dosage of light is in the range of 30 J/cm<sup>2</sup> to 100 J/cm<sup>2</sup>.
5. A method according to claim 1, wherein the effective repetitive dosage of light is administered over a treatment period in the range of about 10 to 40  
20 minutes.
6. A method according to claim 1, wherein the effective repetitive dosage is administered daily or every second day.
- 25 7. A method according to claim 1, wherein the effective repetitive dosage of light is administered throughout the time period that a person is undergoing orthodontic treatment.
8. A method according to claim 1, wherein the light has a wavelength in  
30 the range of about 585 nm to about 665 nm.
9. A method according to claim 8, wherein the light has a wavelength in the range of about 605 nm to about 645 nm.

- 31 -

10. A method according to claim 8, wherein the light is used to promote the bodily motion of teeth through the person's alveolar bone.
11. A method according to claim 1, wherein the light has a wavelength in the range of about 815 nm to about 895 nm.
12. A method according to claim 11, wherein the light has a wavelength in the range of about 835 nm to about 855 nm.
13. A method according to claim 11, wherein the light is used to increase the velocity of tooth movement through the person's alveolar bone when the teeth are to be moved in a tipped orientation.
14. A method according to claim 1, wherein the light has a wavelength in the range of about 640 nm to about 680 nm.
15. A method according to claim 1, wherein the light has a wavelength in the range of about 740 nm to about 780 nm.
16. A method according to claim 1, wherein teeth in a region of the person's maxillary and mandibular alveolar bone to which light is not applied are used as an anchor to facilitate movement of teeth in the selected region.
17. A method according to claim 1, wherein an effective repetitive dosage of light is applied to a plurality of selected regions of the person's maxillary and mandibular alveolar bone.
18. A method of selectively regulating tooth movement during orthodontic treatment of a person, comprising the steps of:
- applying an effective repetitive dosage of light having a first wavelength extra-orally to a selected first region of the person's maxillary and mandibular alveolar bone; and

- 32 -

applying an effective repetitive dosage of light having a second wavelength extra-orally to a selected second region of the person's maxillary and mandibular alveolar bone.

- 5 19. A method according to claim 18, wherein the first and second regions together comprise substantially the entirety of the person's maxillary and mandibular alveolar bone.
20. A method according to claim 18, wherein the effective repetitive  
10 dosage of light is in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>.
21. A method according to claim 20, wherein the effective repetitive dosage of light is in the range of 30 J/cm<sup>2</sup> to 100 J/cm<sup>2</sup>.
- 15 22. A method according to claim 18, wherein the first wavelength is in the range of about 585 nm to about 665 nm, and wherein the second wavelength is in the range of about 815 nm to about 895 nm.
23. A method according to claim 22, wherein the first wavelength is about  
20 625 nm and the second wavelength is about 855 nm.
24. A method according to claim 18, wherein teeth in a region of the person's maxillary and mandibular alveolar bone to which light is not applied are used as an anchor to facilitate movement of teeth in the selected region.
- 25 25. A method according to claim 18, wherein the effective repetitive dosage of light having the first wavelength is applied to a first plurality of selected regions of the person's maxillary and mandibular alveolar bone, and wherein the effective repetitive dosage of light having the second wavelength  
30 is applied to a second plurality of selected regions of the person's maxillary and mandibular alveolar bone.
26. A method for stabilizing teeth of a person following completion of orthodontic treatment, comprising applying an effective repetitive dosage of

- 33 -

light having a wavelength in the range of about 585 nm to about 665 nm extra-orally to a selected region of the person's maxillary and mandibular alveolar bone when orthodontic treatment is fully or substantially complete.

- 5 27. A method for stabilizing teeth of a person following completion of orthodontic treatment, comprising applying an effective repetitive dosage of light having a wavelength in the range of about 815 nm to about 895 nm extra-orally to a selected region of the person's maxillary and mandibular alveolar bone when orthodontic treatment is fully or substantially complete.
- 10 28. A method according to claim 26 or 27, wherein the selected region comprises substantially the entirety of the person's maxillary and mandibular alveolar bone.
- 15 29. A method according to claim 26, wherein the wavelength is in the range of about 615 nm to about 635 nm.
30. A method according to claim 26 or 27, wherein a retainer device or a passive orthodontic appliance is used on the person.
- 20 31. A method according to claim 26 or 27, wherein the repetitive dosage is in the range of 24 J/cm<sup>2</sup> to 200 J/cm<sup>2</sup>.
32. A method according to claim 31, wherein the repetitive dosage is in  
25 the range of 30 J/cm<sup>2</sup> to 100 J/cm<sup>2</sup>.
33. A method according to claim 26 or 27, wherein the effective repetitive dosage is administered in periodic intervals.
- 30 34. A method according to claim 33, wherein the periodic intervals are every second day, weekly, or biweekly.
35. An apparatus for selectively regulating tooth movement during the orthodontic treatment of a person, the apparatus comprising:

- 34 -

a support sized and shaped to engage with features of a person's face;  
and

5 a plurality of light sources associated with the support and configured  
to deliver light extra-orally substantially uniformly to selected regions of a  
person's maxillary and mandibular alveolar bone.

10 36. An apparatus according to claim 34, wherein the plurality of light  
sources are positioned and disposed to permit light to be delivered to  
substantially the entirety of the person's maxillary and mandibular alveolar  
bone.

37. An apparatus according to claim 35, wherein the plurality of light  
sources are independently operable.

15 38. An apparatus according to claim 35, wherein the light sources include  
first light emitters adapted to emit light having a wavelength in the range of  
about 585 nm to about 665 nm, and second light emitters adapted to emit  
light having a wavelength in the range of about 815 nm to about 895 nm.

20 39. An apparatus according to claim 35, wherein the support is configured  
to bias at least one of the light sources against skin of the person's face.

25 40. An apparatus according to claim 35, further comprising a reflectance  
sensor associated with the support and positioned so as to be adjacent the skin  
of the person when the apparatus is in a use position.

30 41. An apparatus according to claim 35, wherein portions of the support  
include a track formed on an inner surface of the portions, and wherein the  
plurality of light sources include a track-engaging ridge shaped and disposed  
for engagement with the track to secure the light sources to the support.

42. An apparatus according to claim 35, further comprising a heat sink  
coupled to each one of the light sources.

- 35 -

43. An apparatus according to claim 42, wherein portions of the support include a track formed on an inner surface of the portions, and wherein the heat sink includes a track-engaging ridge shaped and disposed for engagement with the track to secure the light sources to the support.

5

44. An apparatus according to claim 35, wherein the light sources comprise a plurality of light emitting diodes.

45. An apparatus according to claim 35, wherein the light sources  
10 comprise a plurality of vertical cavity surface emitting lasers.

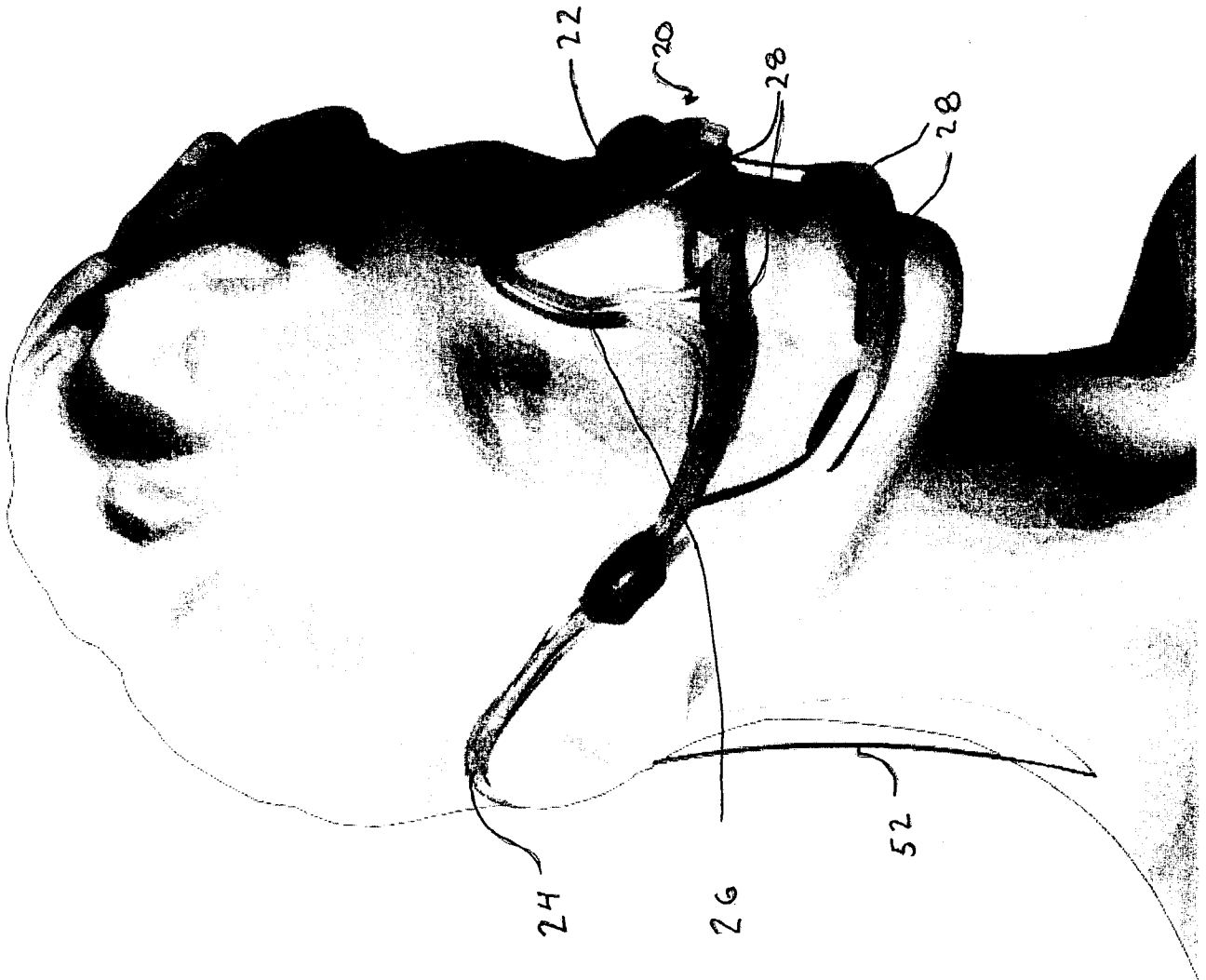


FIG. 1

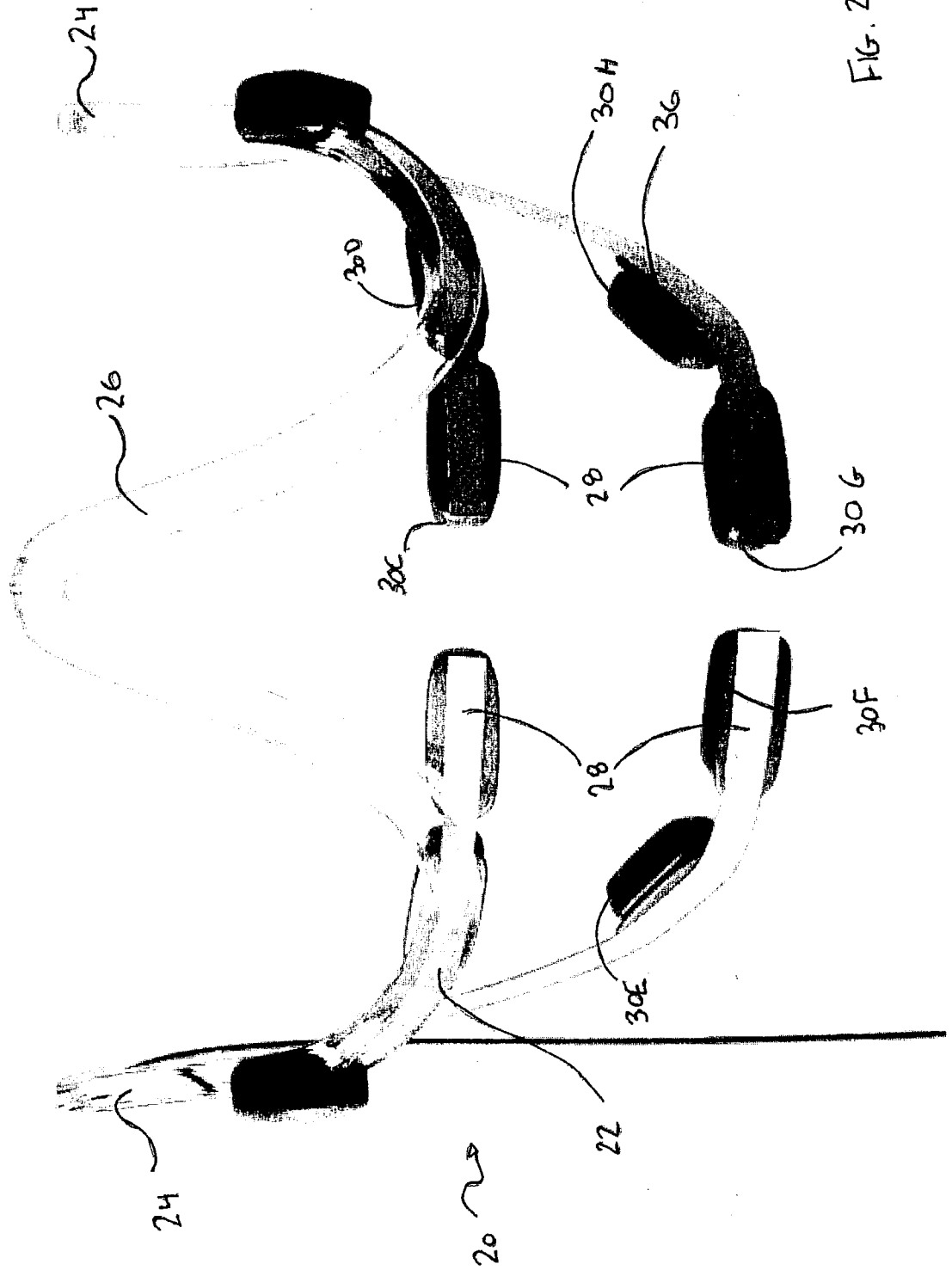


FIG. 2

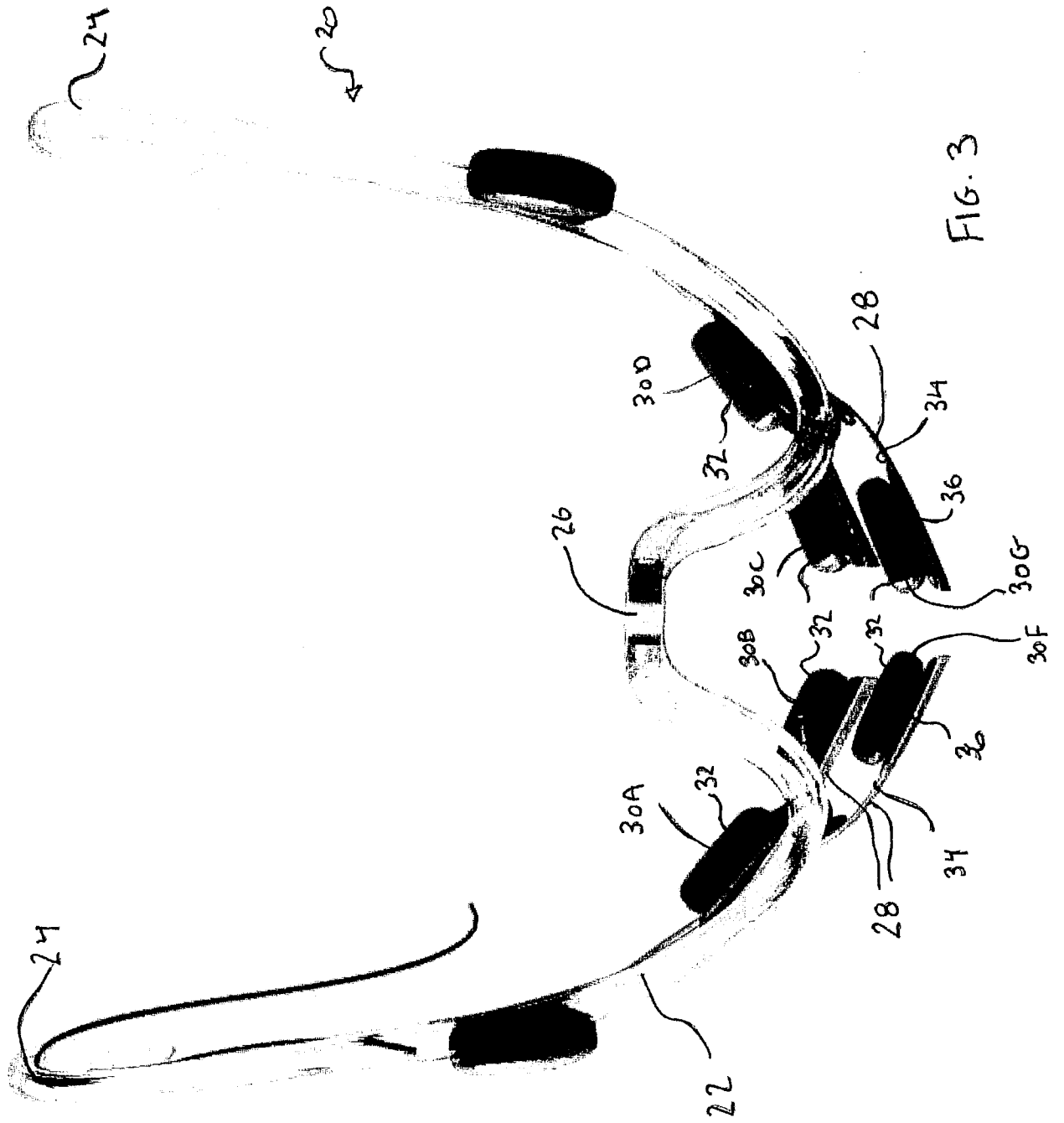


FIG. 3

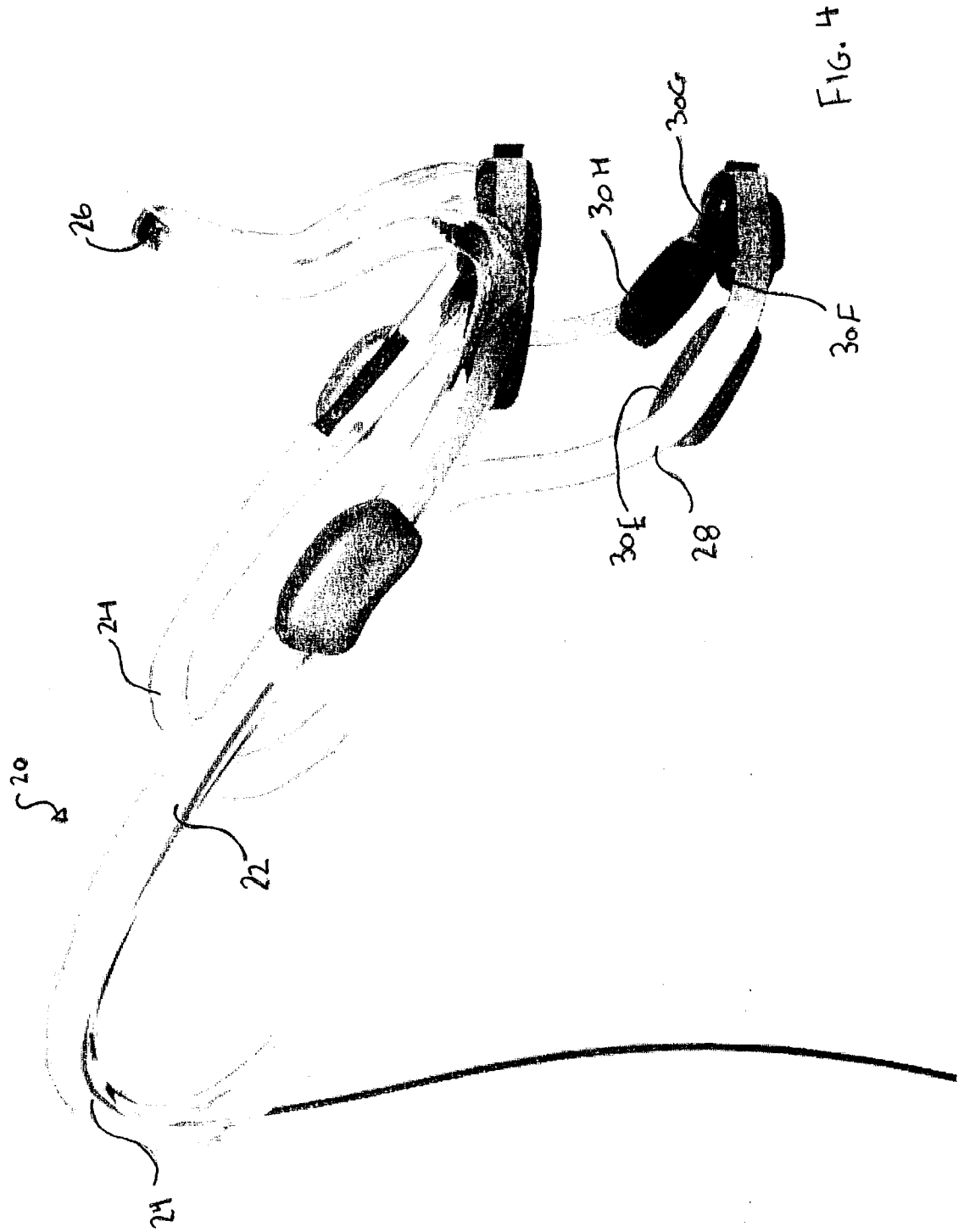


FIG. 4

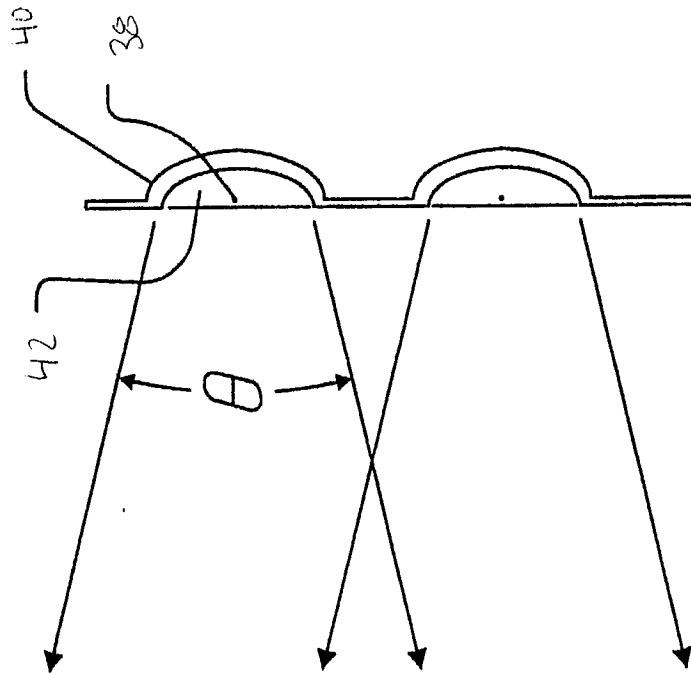


FIG. 5

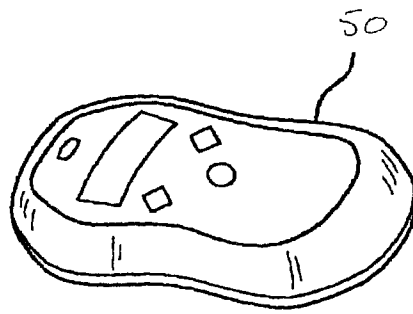


FIG.6

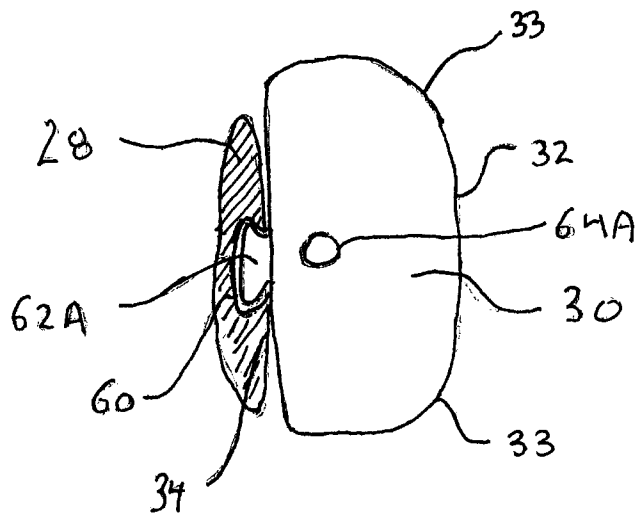


FIG. 7A

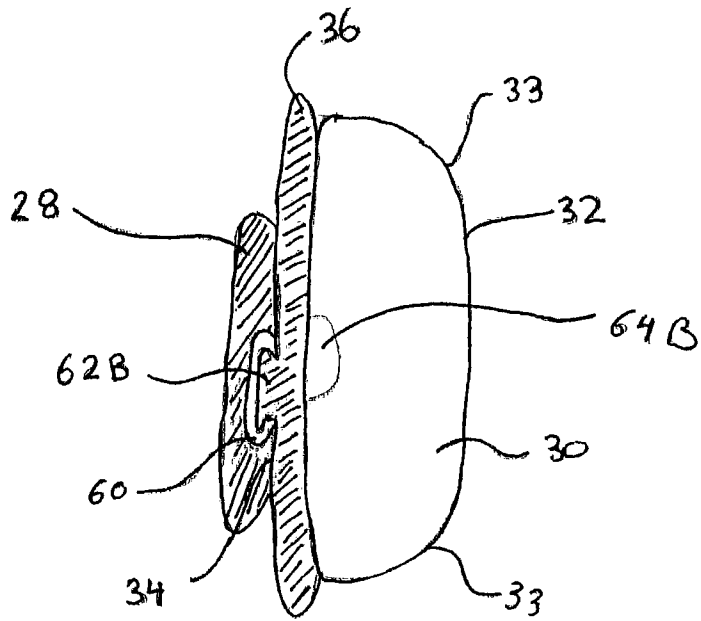


FIG. 7B

**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/CA2009/000808

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC: *A61N 5/06* (2006.01) , *A61N 5/067* (2006.01) , *A61C 7/08* (2006.01) , *A61C 7/00* (2006.01)  
 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)  
 A61N\*(2006.01)(all subgroups including keywords)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)  
 Canadian Patent Database, EPOQUE, USPTO West, Delphion, Google (keywords: light, treatment, ortho\*, dental, jaw, bone, mandib\*, maxill\*)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0248930 A1 (Brawn) 25 October 2007 (25-10-2007) * figure 1 * paragraph 46 * claim 10	35-45
X	US 2006/0200212 A1 (Brawn) 7 September 2006 (07-09-2006) * figure 1 * claim 25	35-44
A	US 2008/0255498 A1 (Houle) 16 October 2008 (16-10-2008) * see entire document	35-45
A	US 2006/0085052 A1 (Feuerstein et al.) 20 April 2006 (20-04-2006) * see entire document	35-45

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

* Special categories of cited documents :	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 2 March 2010 (02-03-2010)	Date of mailing of the international search report 4 March 2010 (04-03-2010)
--	---

Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Saadia Khan (819) 934-6752
---	--

**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/CA2009/000808**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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.  Claim Nos. : 1-34  
because they relate to subject matter not required to be searched by this Authority, namely :  
  
Claims 1-34 are considered to be directed to a method of medical treatment which the International Search Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1 (iv).
2.  Claim 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.  Claim 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 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 claim 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 claim 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/CA2009/000808

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US2007248930A1	25-10-2007	CA2598189A1	24-08-2006
		EP1853347A1	14-11-2007
		EP1853347A4	30-04-2008
		US2006200212A1	07-09-2006
		US2007248930A1	25-10-2007
		WO2006087633A1	24-08-2006
US2006200212A1	07-09-2006	WO2009000075A1	31-12-2008
		CA2598189A1	24-08-2006
		EP1853347A1	14-11-2007
		EP1853347A4	30-04-2008
		US2006200212A1	07-09-2006
		US2007248930A1	25-10-2007
US2008255498A1	16-10-2008	WO2006087633A1	24-08-2006
		WO2009000075A1	31-12-2008
		CA2632183A1	01-03-2007
		EP1933941A2	25-06-2008
		US2008255498A1	16-10-2008
		WO2007025244A2	01-03-2007
US2006085052A1	20-04-2006	WO2007025244A3	15-11-2007
		WO2007025244B1	27-12-2007
		US2006085052A1	20-04-2006