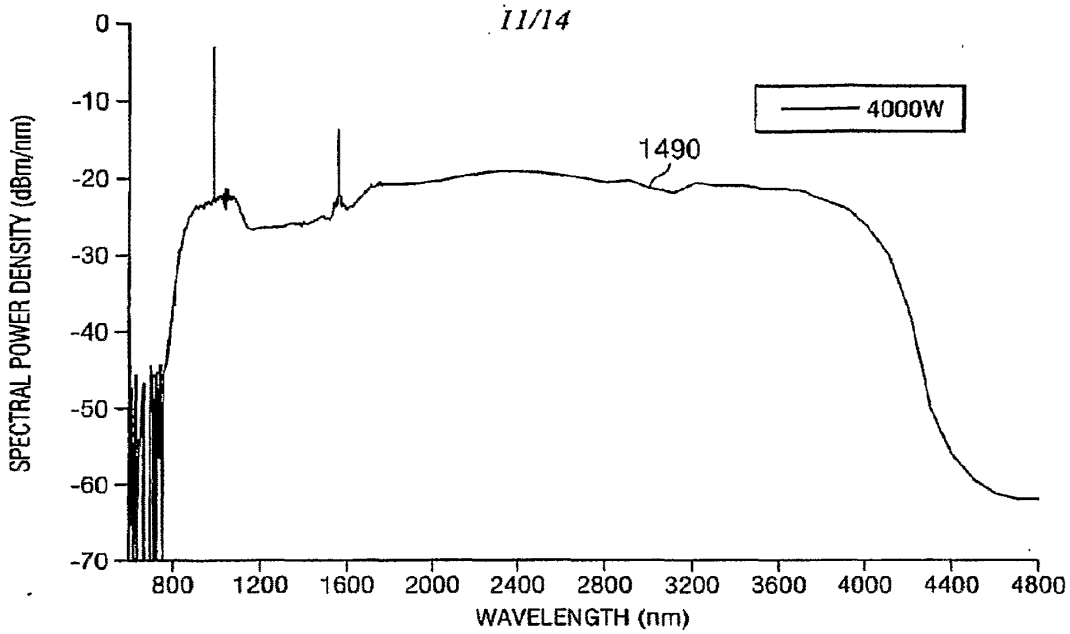


FIG. 14c

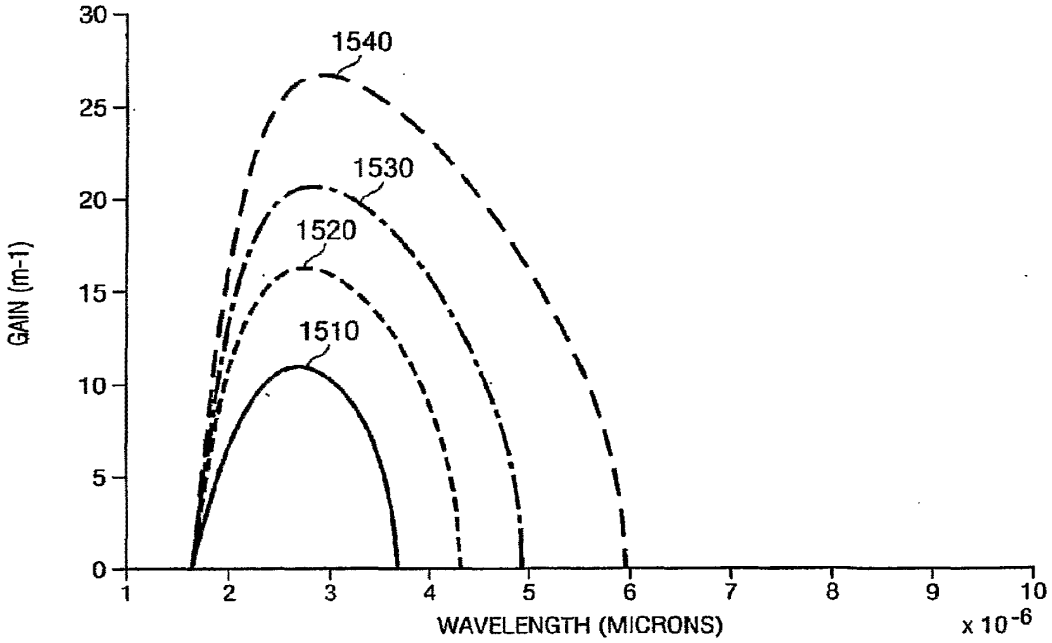


FIG. 15

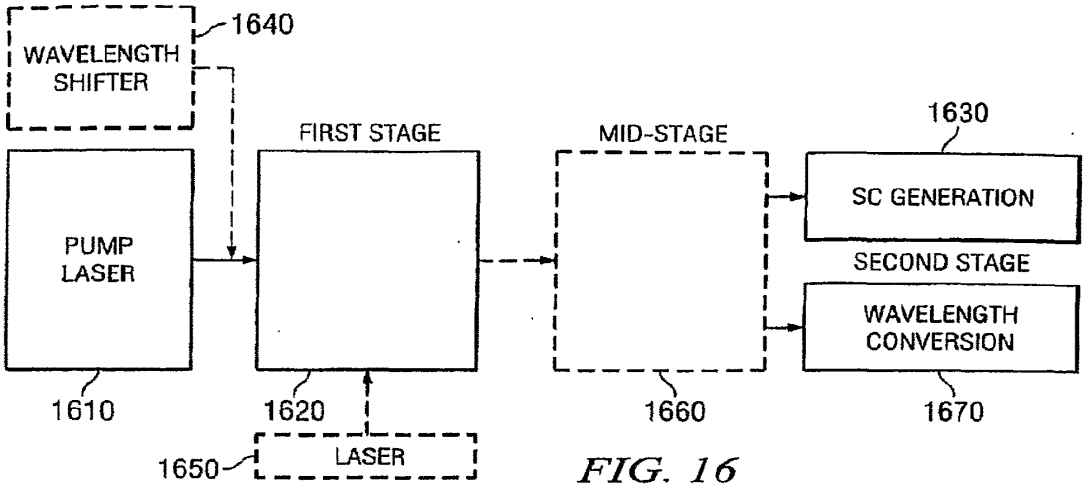


FIG. 16

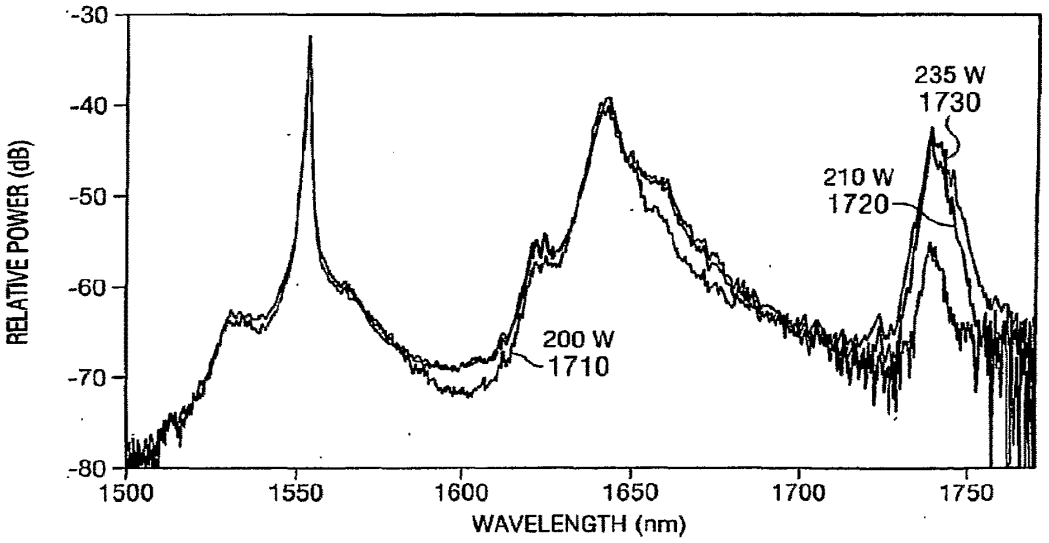


FIG. 17a

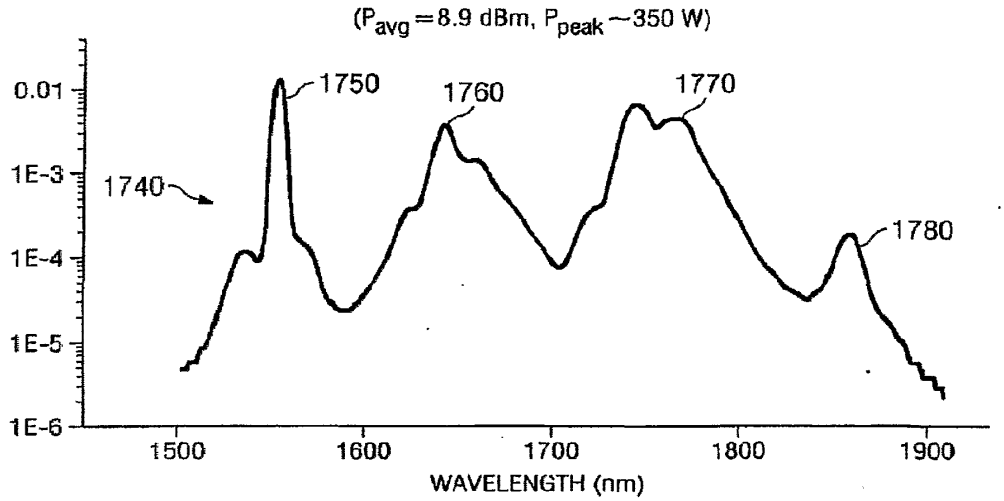


FIG. 17b

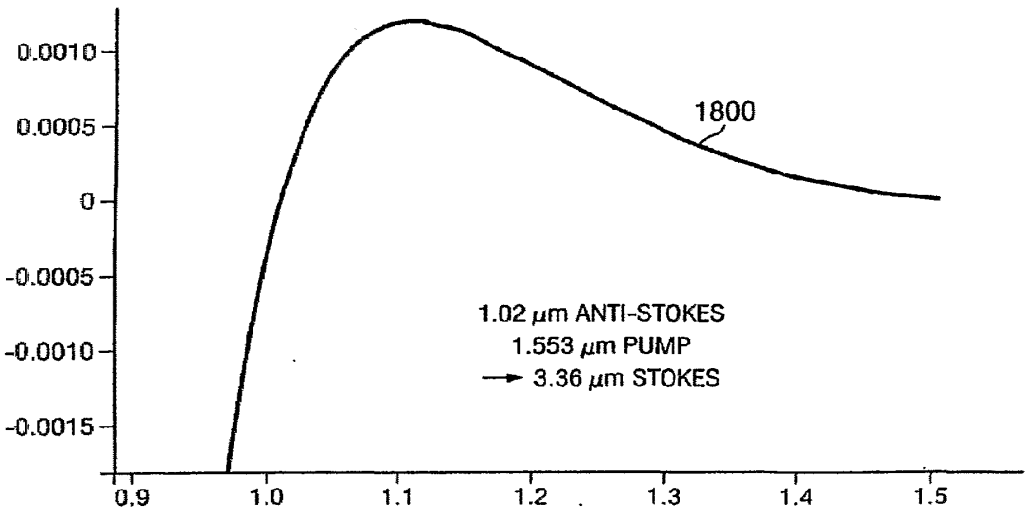


FIG. 18

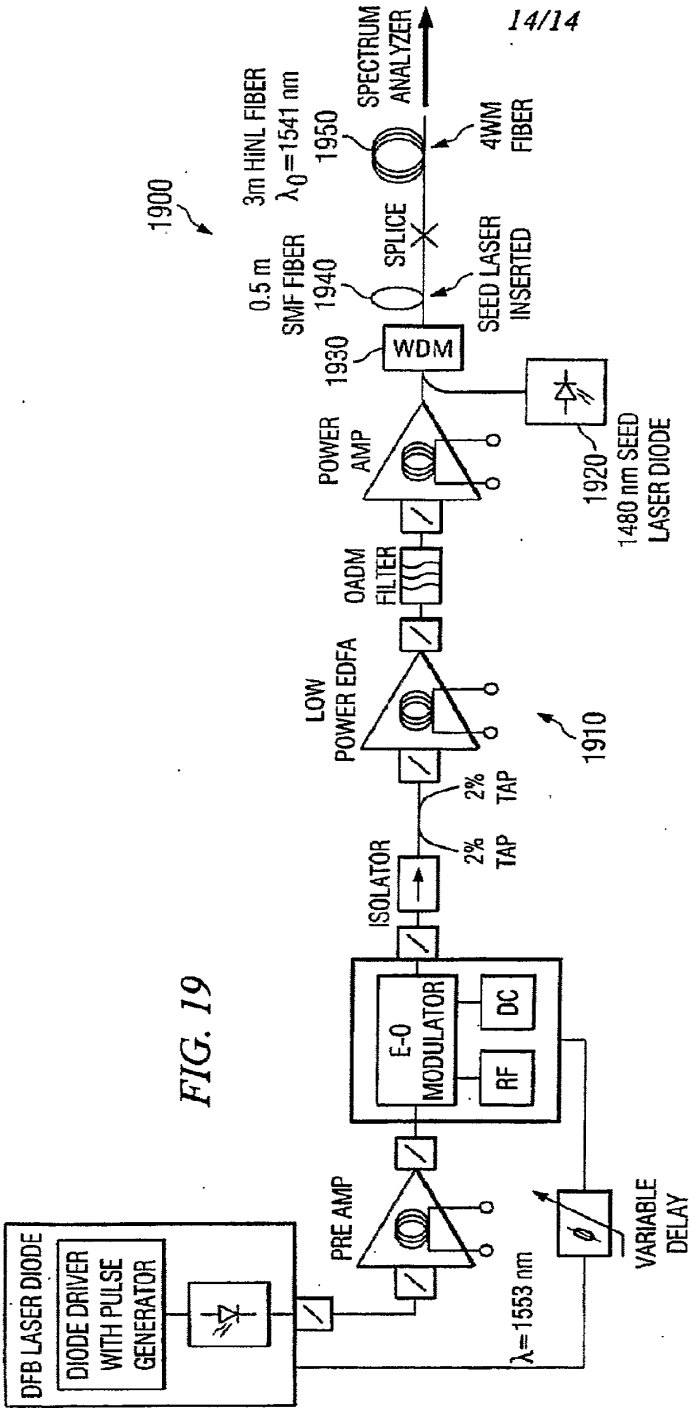

1900
3m HiNL FIBER
λ_0=1541 nm
1950
SPECTRUM ANALYZER
4WM FIBER
0.5 m SMF FIBER
1940
SPLICE
SEED LASER INSERTED
1930
WDM
POWER AMP
1920
1480 nm SEED LASER DIODE
OADM FILTER
LOW POWER EDFA
1910
2% TAP
2% TAP
ISOLATOR
E-O MODULATOR
DC
RF
PRE AMP
VARIABLE DELAY
λ=1553 nm
DFB LASER DIODE
DIODE DRIVER WITH PULSE GENERATOR

FIG. 19

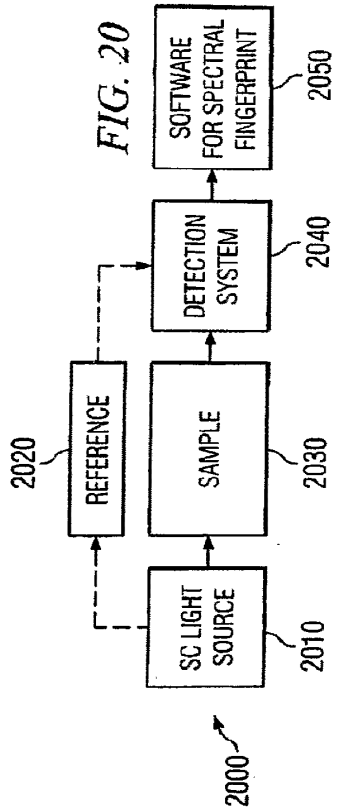

2000
SC LIGHT SOURCE
2010
REFERENCE
2020
SAMPLE
2030
DETECTION SYSTEM
2040
SOFTWARE FOR SPECTRAL FINGERPRINT
2050

FIG. 20

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(54) **Title**: DENTAL IMAGING AND APPARATUS THEREFOR

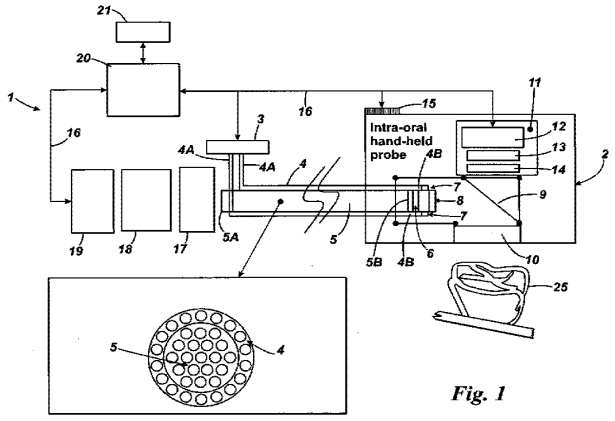


Fig. 1

(57) **Abstract**: Apparatus and method for imaging a tooth. The apparatus includes: illumination means arranged to generate first and second infra-red light; and image data acquisition means arranged for receiving infra-red light originating from the illumination means and returned from an illuminated tooth. The image data acquisition means includes infra-red pixel sensor means responsive to said returned infra-red light to generate image pixel values for a first image of the illuminated tooth using first infra-red light and for a second image of the illuminated tooth using second infra-red light. The apparatus further includes data processing means to use one or more image pixel values of the first image to calculate a first reflectance value, and to use one or more image pixel values of the second image to calculate a second reflectance value, and to determine from the first and second reflectance values a measure of the degree of enamel lesion (Se) and/or dentin lesion (Sd) present in the part.

DENTAL IMAGING AND APPARATUS THEREFOR

The present invention relates to methods and apparatus for the imaging of teeth and particularly, though not exclusively, for imaging lesions or for processing such data.

Dental caries is a dynamic disease characterised by tooth demineralization leading to an increase in the porosity of the enamel surface. The result is commonly known as "white spots" and is due to the white appearance created by the increase of refraction index of de-mineralized enamel. Leaving these lesions untreated can potentially lead to dental cavities which may reach the dentin and pulp of the tooth, and may eventually cause tooth loss. Occlusal and approximal tooth surfaces are among the sites most susceptible to de-mineralization due the acid attack from bacterial by-products.

The use of preventive agents to inhibit, or reverse, the de-mineralization process is predicated on the detection of lesions at an early stage. However, detecting early lesions is difficult.

Non-invasive detection of white spots may employ an estimation of surface porosity or mineral loss. Although radiographic methods are suitable for approximal surface lesion detection, they offer a reduced utility for screening early caries in occlusal surfaces. In addition, radiographic methods are not ideal due to the patient exposure to x-rays and to their lack of sensitivity at very early stages of the disease. Electrical caries monitoring enables only single point measurements.

Optical methods offer non-destructive monitoring of early tooth enamel de-mineralization.

Current imaging methods are based on the observation of changes in light transport within the tooth, namely

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absorption, scattering and/or fluorescence of light. Porous media scatters more the light than uniform media and stain tends to absorb the light. Trans-illumination is a method that looks for shadows created by pumping white light from one side of the tooth, as viewed from the opposite side. Such shadows may correspond to regions where light is scattered away and/or absorbed. This technique is difficult to employ quantitatively due to an uneven light distribution inside the tooth. Quantitative light fluorescence (QLF) is an imaging method that relies on the natural fluorescence by teeth. This fluorescence acts as an internal source of light that will try to escape through the surface of the tooth. With appropriate filters, one may observe the fluorescent light and may quantify the loss of mineral by visualizing dark patches or shadows produced by scattering and/or absorption of fluorescent light. However this technique is unsuitable when trying to discriminate between white spots and stain as both produce the similar effect.

Stain is commonly observed in the occlusal sites of teeth and this obscures the true detection of caries. Stain, therefore, is one of the most confounding factors in the detection of early caries lesions.

The present invention may desirably be employed in addressing or overcoming limitations in the prior art.

At its most general, the invention proposed is spectral measurement or imaging of a tooth in infra-red light (e.g. the near infra-red (NIR) spectral region) to produce data to enable identification and/or quantification of lesions on a tooth (e.g. occlusal tooth surfaces) using the spectral signatures of water absorption and the effect of porosity or demineralisation in the scattering of light by a tooth.

Near-infrared (NIR) light has a number of advantages for use in caries detection as compared to visible light since it

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suffers a lower degree absorption by stain and may penetrate deeper into a target tooth. Infra-red light may be employed (e.g. for Hyperspectral images) having a wavelength from 1000nm to 2500nm or more. The measured effects of infra-red light scattering by porous enamel and absorption thereof by water in dentin may be used to quantify the lesion extension and generate a caries score quantifying the degree of lesion. Analysis of the reflectance spectra of a target tooth illuminated by infra-red light may identify infra-red wavelength values, or ranges, of illuminating light returned from a tooth which exhibit reflectance values characteristic of scattering by porous or demineralized enamel or absorption thereof by water in the tooth (e.g. in dentin).

Histological examination of ground target teeth, made after the spectral measurements have shown that a caries score obtained according to an aspect of the invention, correlates significantly (Pearson's correlation of 0.89, $p < 0.01$) with the corresponding histological score. Results yield a sensitivity of 75% and a specificity of 87.5% for enamel lesions and a sensitivity of 87.5% and a specificity of 100% for dentine lesions. The nature of the technique may provide a number of advantages including, desirably, the ability to spatially map the lesion distribution rather than only obtaining single-point measurements. The technique may be non-invasive, and/or non-contact and and/or stain-insensitive.

Using light in the infra-red, e.g. near infra-red, region of the electromagnetic spectrum may overcome difficulties associated with scattering and absorption. Scattering in enamel is reduced and absorption by stain is low when infra-red light is employed. In fact, the scattering by enamel tissues reduces in the form of $1/\lambda^3$ laser wavelengths, λ, of 512 nm, 632 nm and 1053 nm at least. In addition, a higher transparency for 1310nm wavelength light than for 1550nm wavelength light in sound enamel suggests that water in the enamel attenuates the light at higher wavelengths. Stimulated

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lesions in tooth samples up to 6.75mm in thickness can be resolved with a contrast ratio greater than 0.35 as between sound and demineralised enamel by using light of wavelength 1310nm.

In a first of its aspects, the invention may provide apparatus for imaging a tooth including: illumination means arranged to generate first infra-red light with a first wavelength having a value within a range of values corresponding to an infra-red spectral absorption band of water (e.g. a spectral absorption band of water within a tooth, such as within enamel and/or within dentin), to generate second infra-red light with a second wavelength having a value within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel, and for illuminating a tooth therewith; image data acquisition means arranged for receiving infra-red light originating from the illumination means and returned from an illuminated tooth, and including infra-red pixel sensor means responsive to said returned infra-red light to generate image pixel values for a first image of the illuminated tooth using first infra-red light and not second infra-red light and to generate image pixel values for a second image of the illuminated tooth using second infra-red light and not first infra-red light, and to provide such image pixel values for use.

In this way, a signature of enamel lesion and/or a signature of dentin lesion may be sought in the spectrally selected image data for a tooth. In generating corresponding spectrally separated images, one may ensure that corresponding parts of each image may be identified as being associated with a common part of a tooth. This avoids misalignment or movement problems common in single-point data acquisition methods.

The infra-red pixel sensor array may comprise a CCD sensor array, or an InGaAs sensor array, or a sensor array such as a

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Mercury Cadmium Telluride (MCT) sensor array. An InGaAs sensor array may have a spectral response that covers up to 1700nm whereas MCT sensor array may be responsive to infra-red wavelengths up to 2500nm.

The infra-red pixel sensor array may be preferentially responsive to near-infrared wavelengths such as wavelengths in the range 0.8 microns to 2.5 microns, or 1.0 microns to 2.5 microns. The second wavelength may have a value which also falls within a range of values corresponding to an infra-red spectral absorption band of water (e.g. water in a tooth). The illumination means may be arranged to generate infra-red light with a third wavelength (other than the first or second wavelength) having a value within a range of values corresponding to an infra-red spectral absorption band of water (e.g. water in a tooth) and/or within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel.

The infra-red pixel sensor means may be arranged to be responsive to returned infra-red light originating from the illumination means to generate third image pixel values for a third image of the illuminated tooth using third infra-red light and not first nor second infra-red light. The apparatus may provide such third image pixel values for use, such as for use in detecting therein a signature of enamel lesion and/or dentin lesion. Most preferably, the infra-red pixel sensor means is responsive to returned infra-red light of a reference wavelength other than the first, second or third wavelengths, and originating from the illumination means, to generate reference image pixel values or for a reference image of the illuminated tooth using the reference infra-red light, and to provide them for use. The reference image pixel values may be used by the apparatus in, for example, normalising any image pixel value of any one, some or all of first, second or third images.

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Preferably all of the first, second, third and reference infra-red wavelengths are less than 3 microns in size, e.g. within the near-IR band (e.g. from 0.8 microns to 2.5 microns). It has been found that infra-red wavelengths exceeding about 3 microns suffer significant attenuation in tooth enamel. This may reduce the intensity of illuminating infra-red light reaching dentin underneath such enamel, and may, to a varying extent, confound generation of a spectral signature in returned infra-red light characteristic of water within dentin indicative of dentin lesion.

The first wavelength may be a value chosen from the range 1410nm - 1470nm. The second wavelength may be a value chosen from the range 1580nm - 1640nm. The third wavelength may be a value chosen from the range 1880nm - 1940nm. The reference wavelength may be a value chosen from the range 1060nm - 1120nm. In each case, the wavelength may be within a narrower range being one half, or one third, or one sixth, of the size of the respective range given above, centred upon the same central wavelength as in the ranges given above.

The image data acquisition means may include optical input means via which the apparatus is arranged to receive infra-red light returned from an illuminated tooth in a direction substantially parallel with, or subtending an acute angle with respect to, a direction of illumination by the illumination means.

For example, back-scattering or back-reflection of illuminating light is preferred since the spectral signature of back-scattered light may be relatively strong in such circumstances when arising due to porosity in the tooth enamel. Also, this simplifies the arrangement and use of the apparatus and allows for a compact probe-like apparatus.

The illumination means may comprise optical output means with an optical axis along which the apparatus is arranged to

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output said infrared light to illuminate a tooth. The image data acquisition means may include optical input means comprising an optical axis along which the apparatus is arranged to receive infrared light returned from an illuminated tooth and which is substantially parallel to, or subtends an acute angle with respect to, the optical axis of the illumination means. Thus, back-scattering of infra-red light from the illumination means by an illuminated tooth, and to the optical input means may be provided. Preferably, the subtended angle is as small as is practicable, such as 5° or less, or less than 2° or less than 1°.

The image data acquisition means may include camera means including a pixel sensor array responsive to visible light returned from an illuminated tooth to form one or more image pixel values representing an image of at least a part of the tooth.

Accordingly, a "visible" image, i.e. representing what may be perceived by the human eye, may be simultaneously or contemporaneously created to permit images of the tooth formed using infra-red light to be compared with the "visible" image. The visible image may be co-registered or pixel-wise aligned with images formed using infra-red light to permit a pixel(s) selected in the "visible" image to directly identify a pixel(s) in an image of the same target formed using infra-red, by association with the same tooth part.

The apparatus may include infra-red optical filter means selectively operable in a first state to transmit infra-red light originating from the illumination means having said first wavelength and to substantially prevent transmission therethrough of infra-red light having said second wavelength, and in a second state to transmit infra-red light originating from the illumination means having said second wavelength and to substantially prevent transmission therethrough of infra-red light having said first wavelength. The infra-red optical

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filter means may be selectively operable in a third state to transmit infra-red light originating from the illumination means having said third wavelength and to substantially prevent transmission therethrough of infra-red light having any of said first wavelength and said second wavelength. The infra-red optical filter means may be selectively operable in a fourth state to transmit infra-red light originating from the illumination means having a reference (fourth) wavelength and to substantially prevent transmission therethrough of infra-red light having any of the first, second, or third wavelengths. Thus, spectrally separated and distinct first, second, third or reference infra-red image data may be acquired in this way, or otherwise. In alternatives, the illumination means may comprise means for separately (physically) generating infra-red light spectrally separated in this way for illuminating a tooth. Examples include an array of separate infra-red light sources (e.g. LEDs) each one of which is arranged to generate only one of the first, second, third and reference wavelengths. A visible light source may be provided separately in this way for use in enabling said "visible" images. In other examples, the infra-red pixel sensor means may comprise separate groups of pixel sensors in which each pixel sensor of a respective group is served by a dedicated one of a plurality of different infra-red optical filters. For example, four separate pixel sensor arrays may be provided each one of which is served by a respective one of four different infra-red optical filters arranged to transmit a respective one (only) of the first, second, third and reference infra-red wavelengths discussed above. The separate groups of pixel sensors may be arranged in a common overall pixel array (e.g. pixel sensor chip) overlaying separate individual sensor pixels of which (e.g. separately or in defined areas) are respective infra-red optical filters. In this example, the infra-red pixel sensor means may comprise an active-pixel sensor array in which individual pixels of the sensor are addressable such that pixel sensor signals from individual sensor pixels associated

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with a predetermined filter may be individually obtained and identified as such. The arrangement, in this example, may be analogous to the Bayer-type filter arrangement common in commercial digital cameras.

The infra-red optical filter means may be arranged in optical communication with the infra-red pixel sensor means to filter infra-red light directed to the infra-red pixel sensor means by the image data acquisition means.

The illumination means may include light-source means which may be operable to generate light including said first and second wavelengths and preferably said third wavelength and/or said reference wavelength (e.g. a broadband visible and near-IR source). The infra-red optical filter means may be arranged in optical communication with the light-source means to filter light generated by the light-source means for illuminating a tooth with infra-red radiation transmitted by the infra-red optical filter means.

The illumination means may comprise light-source means operable to generate light including said first and second wavelengths, (and preferably also the third and/or reference wavelength, and preferably visible wavelengths) and optical output means remotely or locally in optical communication with the light-source means via output optical waveguide means and arranged to output from the apparatus light generated by the light-source means to illuminate a tooth.

The apparatus may include optical input means remotely or locally in optical communication with the infra-red pixel sensor means via input optical means (e.g. optical waveguide means) and arranged to receive infra-red light returned from an illuminated tooth and to direct the returned infra-red light to the (local or remote) infra-red pixel sensor means for sensing thereby. The optical input means may not be remote, and may be housed within or otherwise an attachable or

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integral part of a unit or probe device containing the infra-red pixel sensor means. The illumination means may be similarly so housed within or attachable to the unit or probe device.

The apparatus may include an intra-oral probe (e.g. hand held) comprising the optical input means and the optical output means. This probe may be remote from image pixel sensor means and/or the illumination means, or the probe may include the image pixel sensor means and/or the illumination means.

For example, the probe may comprise any one, some or all of: the infra-red pixel sensor means; the illumination means; the infra-red optical filter means; any optical elements intermediate the infra-red pixel sensor means and the optical input means for collecting, focussing, collimating or otherwise preparing returned infra-red light. The probe may comprise such elements in a detachable unit attachable to the rest of the probe via attachment means or adapter means to place those elements in operable and optical communication with the optical input/output means.

Thus, different detachable such units may be provided having different operating characteristics (e.g. filters, illumination means or light source, sensor array etc) as required, enabling rapid and simple alteration of the operating characteristics of the probe as a whole.

The input optical waveguide means may comprise one or more optical fibres which collectively define an aligned optical fibre bundle.

The output optical waveguide means may comprise one or more optical fibres collectively defining an aligned optical bundle.

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Optionally, at least a terminal end of the output optical waveguide means is adjacent the optical input means.

Optionally, the terminal end of the output optical waveguide comprises a bundle of optical fibres the ends of which form a ring circumscribing the output optical waveguide.

The illumination means may comprise first optical polarizer means for polarizing according to a first polarization axis infra-red radiation generated by the illumination means, and the image data acquisition means comprises second optical polarizer means for polarizing according to a second polarization axis transverse to the first polarization axis infra-red radiation received thereby from an illuminated tooth. The first and second optical polarizer means may be individually arranged to linearly polarise light, or to elliptically or circularly polarise light received thereby. Preferably, each is arranged to linearly (or optionally elliptically) polarise light, and may be such that the first and second optical polarisers define a pair of crossed polarisers. Specular reflections of light from tooth enamel tends to at least partially polarise un-polarised incident light, or put another way, specular reflections from a tooth surface preferentially select polarised light. Illuminating light returned from a tooth by a scattering process (e.g. multiple reflections) tends to de-polarise polarised incident light. Consequently, requiring returned light to pass through a polarising filter with a polarising characteristic converse to that of the filter through which illuminating light passed, to some extent removes from returned light those parts preserving the converse polarisation (e.g. specularly reflected light).

The optional use of circular polarisers to polarise light returned from an illuminated tooth has been found to enhance image contrast and definition.

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The image data acquisition means may comprise focussing means arranged to form upon the infra-red pixel sensor means a real optical image using infra-red light received by the image data acquisition means from an illuminated tooth. Alternatively, or additionally, the image data acquisition means may comprise within-probe focussing means arranged to form a focused image upon a terminal optical input end of an aligned optical fibre bundle defining the input optical waveguide means, using return illuminating infra-red light. Most preferably the input end of the input optical waveguide comprises a flat surface collectively formed by a plurality of closely-packed ends of optical fibres. In this way, the light of a focused infra-red image may be transmitted, conveyed or guided from within the probe to the infra-red pixel sensor means (optionally remote). The focussing means (intra-probe or remote) may possess a controllable "zoom" function (e.g. a variable focal length) controllable by the user of the apparatus.

The optical filter means, the focussing means and infra-red pixel sensor means may be each in mutual optical communication and locally or remotely in optical communication with the optical input means (e.g. via said input optical waveguide means when remote).

Preferably, the illumination means is arranged to deliver full-field illumination to the tooth to be imaged, in other words to illuminate the whole area of the tooth which is to be imaged, e.g. substantially the whole exposed area of the tooth. In this way, the image pixel values of the area which is to be imaged can be generated without requiring the illumination means to be scanned across the area, as might be required if the illumination means only delivered only point-like illumination. The illumination means may be arranged to deliver full-field illumination e.g. by selection of suitable light source means and/or output optical waveguide means.

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Similarly, it is also preferable for the infra-red pixel sensor means to be arranged to detect or capture a full-field image of the tooth, in other words to capture an image of the tooth without it having to be scanned across the tooth. For example, the infra-red pixel sensor means may comprise an infra-red pixel sensor array as described above. Thus, it is preferable for the apparatus to work on a full-field principle, in which the whole area which is to be imaged of the tooth is illuminated and a corresponding image captured, rather than scanning a point-like illumination across the tooth.

The apparatus may include image processing means arranged to receive said pixel image values for producing one or more of said first, second, third, reference and/or "visible-light" images therefrom.

The image processing means may be arranged to co-register a said first image and a said second image in respect of a common imaged subject, thereby to associate a given image pixel of the first image with a respective image pixel of the second image representing the same part of the imaged subject.

Such co-registration may be performed as between either or both of the first and second images and any or all of the third image and/or the reference infra-red image, and/or any visible image produced by the camera means.

The apparatus may include data processing means arranged in respect of a given part of the imaged subject to use one or more image pixel values of the first image to calculate a first reflectance value (R_1) associated with the part, and to use one or more image pixel values of the second image to calculate a second reflectance value (R_2) associated with the part, and to determine from the first and second reflectance values a measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part. It should be clear that

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in some embodiments, the data processing means may be arranged to determine only a measure of the degree of enamel lesion (S_e) or only a measure of the degree of dentin lesion (S_d) present in the part. However, it is preferable for the data processing means to be arranged to determine both a measure of the degree of enamel lesion (S_e) and a measure of the degree of dentin lesion (S_d) present in the part.

The data processing means may be arranged, in respect of a given said part of the imaged subject, to use one or more image pixel values of the third image to calculate a third reflectance value (R_3) associated with the part, and to determine using first and/or second and/or third reflectance values, a measure of the degree of enamel lesion and/or dentin lesion.

The data processing means may be arranged to use said measure of the degree of enamel lesion (S_e) and said measure of the degree of dentin lesion (S_d) to calculate a measure ($S_{carries}$) of the degree of caries present in the part.

The spectral intensity of a pixel value may be normalised to the reflectance (R_{ref}) obtained at a reference wavelength (e.g. 1090nm) which, preferably corresponds with the highest reflectance (least extinction). The degree of enamel, S_e, and dentin, S_d, lesions may be calculated as follows:

$$S_e = S_e^{(1)} = \frac{R_2}{R_{ref}}$$

or

$$S_e = S_e^{(2)} = \frac{R_1 - R_3}{R_{ref}}$$

$$S_d = \frac{R_2 - R_1}{R_{ref}}$$

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The equation for $S_e^{(2)}$ results in a measure of lesion which has been found to be less susceptible to being influenced by, or confounded by, the effects of specular reflections at the ranges of wavelengths suggested above.

A caries score, S_{caries}, may be calculated as a combination of S_e and S_d. The combination is preferably a weighted algebraic sum of the two terms S_e and S_d, for example, with variable weight factor p:

$$S_{caries} = p\left(\frac{S_e - K_e}{N_e}\right) + (1-p)\left(1 + \frac{S_d - K_d}{N_d}\right)$$

Here, K_x and N_x are an enamel ($x : e$) and dentin ($x : d$) score calibration offset and normalisation factor, respectively. In addition, one may specify that $p = 1$ if

$$\left(1 + \frac{S_d - K_d}{N_d}\right) \prec S_{dth}$$

where S_{dth} represents a dentin lesion threshold, otherwise $p = 0$. Outliers and noise introduced into the data by specular reflections may be removed by limiting the values of the numerators in the equation for S_{caries} to the range $0 < (S_e - K_e) < M_e$ and $0 < (S_d - K_d) < M_d$; here M_e and M_d denote the upper limits. Values outside these limits may be set to zero. The computer means may be operable to perform any one, some or all of the above processing of data.

The infra-red pixel sensor means may be responsive to said returned infra-red light to generate image pixel values for a third image of the illuminated tooth using third infra-red light and not first infra-red light nor second infra-red light, and to provide such image pixel values for use.

The infra-red optical filter means may be selectively operable in a third state to transmit infra-red light originating from the illumination means having said third wavelength and to

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substantially prevent transmission therethrough of infra-red light having any of said first wavelength and said second wavelength.

The data processor means may be arranged to use one or more image pixel values of the third image to calculate a third reflectance value associated with the part, and to determine the measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part using the third reflectance value.

The first wavelength value may be between 1300nm and 1550nm, and the second wavelength value may be between 1550nm and 1800nm. The first wavelength value may be between 1400nm and 1500nm, such as about 1440nm, and the second wavelength value may be between 1550nm and 1650nm, such as about 1610nm.

It is to be understood that the foregoing may represent a physical realisation or implementation of a corresponding method of imaging or measuring a property of a tooth, and that such corresponding methods are encompassed in by the invention.

In a second of its aspects, the invention may provide a method for imaging a tooth including: generating first infra-red light with a first wavelength having a value within a range of values corresponding to an infra-red spectral absorption band of water (e.g. a spectral absorption band of water within a tooth, such as within enamel and/or within dentin), generating second infra-red light with a second wavelength having a value within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel, and illuminating a tooth therewith; receiving at infra-red pixel sensor means first and second infra-red light returned from an illuminated tooth and therewith generating image pixel values for a first image of the illuminated tooth using first infra-red light and not

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second infra-red light and generating image pixel values for a second image of the illuminated tooth using second infra-red light and not first infra-red light, and providing such image pixel values for use.

The method may include receiving infra-red light returned from an illuminated tooth in a direction substantially parallel with, or subtending an acute angle with respect to, a direction of said illumination.

The method may include providing optical output means comprising an optical axis and therealong outputting said infrared light to illuminate a tooth, and providing optical input means comprising an optical axis and therealong receiving infrared light returned from an illuminated tooth for subsequent receipt at the infra-red pixel sensor means wherein the said optical axes are substantially parallel, or subtend an acute angle with respect to each other.

The method may include generating third image pixel values for a third image of the illuminated tooth using third infra-red light returned from the tooth and not first nor second infra-red light. The third image pixel values may be provided for use, such as for use in detecting therein a signature of enamel lesion and/or dentin lesion. The method may include receiving returned infra-red light of a reference wavelength other than the first, second or third wavelengths, and originating from the illumination means, and generating reference image pixel values or for a reference image of the illuminated tooth using the reference infra-red light, and to providing them for use. The reference image pixel values may be used by the apparatus in, for example, normalising any image pixel value of any one, some or all of first, second or third images.

Preferably all of the first, second, third and reference infra-red wavelengths are less than 3 microns in size, e.g.

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within the near-IR band (e.g. from 0.8 microns to 2.5 microns). The first wavelength may be a value chosen from the range 1410nm - 1470nm. The second wavelength may be a value chosen from the range 1580nm - 1640nm. The third wavelength may be a value chosen from the range 1880nm - 1940nm. The reference wavelength may be a value chosen from the range 1060nm - 1120nm. In each case, the wavelength may be within a narrower range being one half, or one third, or one sixth, of the size of the respective range given above, centred upon the same central wavelength as in the ranges given above.

The method may include forming an image representing at least a part of the illuminated tooth using visible light returned therefrom. The method may include co-registering the visible-light image or pixel-wise aligned with images formed using infra-red light to permit a pixel(s) selected in the "visible" image to directly identify a pixel(s) in an image of the same target formed using infra-red, by association with the same tooth part.

The method may include generating light for illuminating the tooth and in a first instance, filtering the light by transmitting through a filter means parts of said light having said first wavelength and substantially preventing transmission through the filter means of parts of said light having said second wavelength; and in a second instance, filtering the light by transmitting through the filter means parts of said light having said second wavelength and substantially preventing transmission through the filter means parts of said light having said first wavelength. The method may include filtering the light by transmitting infra-red light originating from the illumination means having said third wavelength and to substantially preventing transmission of infra-red light having any of said first wavelength and said second wavelength. The method may include filtering the light by transmitting infra-red light originating from the illumination means having a reference (fourth) wavelength and

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to substantially preventing transmission of infra-red light having any of the first, second, or third wavelengths.

The method may include performing said filtering on light directed to the infra-red pixel sensor means.

The method may include performing said filtering on light for illuminating a tooth.

The method may include generating said light remotely from, or locally at, said tooth, guiding the generating light to the proximity of the tooth, and illuminating the tooth with the guided light.

The method may include guiding said returned infra-red light to a location local to, or remote from, the point of receipt of the returned light and generating image pixel values using said returned, guided light at said local or remote location.

The method may be performed using an intra-oral probe.

The method may include polarizing according to a first polarization axis infra-red radiation generated for illuminating a tooth, and polarizing according to a second polarization axis transverse to the first polarization axis infra-red radiation returned from the illuminated tooth. The first and second polarization may be individually linear polarization, or to elliptical or circular polarization. Preferably, each is linear (or optionally elliptical) polarization, and the first and second polarization axes may together define crossed polarization axes.

The method may include forming upon an infra-red pixel sensor means a real optical image using said infra-red light returned from an illuminated tooth.

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The method may include producing one or more of said first, second, third, reference and/or "visible-light" images from said returned light.

The method may include co-registering a said first image and a said second image in respect of a common imaged subject, thereby to associate a given image pixel of the first image with a respective image pixel of the second image representing the same part of the imaged subject. Such co-registration may be performed as between either or both of the first and second images and any or all of the third image and/or the reference infra-red image, and/or any visible image produced by the camera means.

Preferably, the method includes full-field illumination of the tooth, e.g. as described in connection with the first aspect of the invention. Preferably, the method includes detecting or capturing of a full-field image of the tooth, e.g. as described in connection with the first aspect of the invention.

The method may include, in respect of a given part of the imaged subject, calculating a first reflectance value associated with the part using one or more image pixel values of the first image, and calculating a second reflectance value associated with the part using one or more image pixel values of the second image, and determining from the first and second reflectance values a measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part.

The method may include generating image pixel values for a third image of the illuminated tooth using third infra-red light returned from the tooth and not first infra-red light nor second infra-red light, and providing such image pixel values for use.

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The method may include generating light for illuminating the tooth and in a third instance, filtering the light by transmitting through a filter means parts of said light having said third wavelength and substantially preventing transmission through the filter means of parts of said light having any of said first wavelength and said second wavelength.

The method may include calculating a third reflectance value associated with the part using one or more image pixel values of the third image, and determining the measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part using the third reflectance value.

The first wavelength value may be between 1300nm and 1550nm, and the second wavelength value may be between 1550nm and 1800nm. The first wavelength value may be between 1400nm and 1500nm, such as 1440nm or thereabouts, and the second wavelength value may be between 1550nm and 1650nm, such as 1610nm or thereabouts.

The method may include, in respect of a given said part of the imaged subject, using one or more image pixel values of the third image to calculate a third reflectance value (R_3) associated with the part, and determining using first and/or second and/or third reflectance values, a measure of the degree of enamel lesion and/or dentin lesion.

The method may include calculating a measure ($S_{carries}$) of the degree of caries present in the part using said measure of the degree of enamel lesion (S_e) and said measure of the degree of dentin lesion (S_d). The spectral intensity of a pixel value may be normalised to the reflectance (R_{ref}) obtained at a reference wavelength (e.g. 1090nm).

The degree of enamel, S_e, and dentin, S_d, lesions may be calculated according to the method as follows:

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$$S_e = S_e^{(1)} = \frac{R_2}{R_{ref}}$$

or

$$S_e = S_e^{(2)} = \frac{R_1 - R_3}{R_{ref}}$$

$$S_d = \frac{R_2 - R_1}{R_{ref}}$$

A caries score, S_{caries}, may be calculated as a combination of S_e and S_d. The combination is preferably a weighted algebraic sum of the two terms S_e and S_d, for example, with variable weight factor p:

$$S_{caries} = p\left(\frac{S_e - K_e}{N_e}\right) + (1-p)\left(1 + \frac{S_d - K_d}{N_d}\right)$$

Here, K_x and N_x are an enamel ($x : e$) and dentin ($x : d$) score calibration offset and normalisation factor, respectively. In addition, one may specify that $p = 1$ if

$$\left(1 + \frac{S_d - K_d}{N_d}\right) \prec S_{dth}$$

where S_{dth} represents a dentin lesion threshold, otherwise $p = 0$. Outliers and noise introduced into the data by specular reflections may be removed by limiting the values of the numerators in the equation for S_{caries} to the range $0 < (S_e - K_e) < M_e$ and $0 < (S_d - K_d) < M_d$; here M_e and M_d denote the upper limits. Values outside these limits may be set to zero.

In a third of its aspects, the invention may provide a computer programmed to implement the method of the second aspect of the invention.

In a fourth aspect, the invention may provide a computer program product comprising a computer-readable medium

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containing computer executable instructions which implement the method (in part or in full) of the invention in its second aspect when executed on a computer.

In a fifth aspect, the invention may provide a computer program containing computer executable instructions which implement the method of the second aspect when executed on a computer.

In a sixth of its aspects, the invention may provide an apparatus and/or quantitative method for dental caries detection, according to any aspect above, and may be employed to assist in determining the presence of occlusal enamel and/or dentin lesions.

The invention also includes any combination of the aspects and preferred features described except where such a combination is clearly impermissible or expressly avoided.

Preferred embodiments will now be described, by way of example only, with reference to the accompanying drawings of which:

Figure 1 schematically illustrates apparatus including a hand-held intra-oral probe and remote components;

Figure 2 illustrates a selection of spectral images. On the top left is a picture of a tooth taken using visible light. The remaining reflectance images are obtained using near infra-red (NIR) light at the wavelengths indicated;

Figure 3 illustrates NIR spectral reflectance curves from an occlusal tooth surface. The figure shows the reflectance for sound enamel (diamond symbols), an enamel lesion region (asterisks *) and a dentin lesion region (circles ∘). The inset picture shows the location of the points selected within the tooth for this example. Vertical dotted lines in the graph of Figure 3 indicate the wavelengths chosen for the NIR images of Figure 2;

Figure 4 illustrates examples of teeth with different carious lesions. Left-hand images show a picture for each

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tooth obtained in visible light. Central images show the corresponding histological section which is indicated by the straight line traversing the tooth picture, and an arrow indicates the point of view of the section. The right-hand images show the NIR caries maps, spatially scored using a numerical carries score, S_{caries}, for each tooth;

Figure 5 illustrates a correlation plot of the histological score and the average maximum NIR caries score, S_{caries} within the map region corresponding to the histological section;

Figure 6 illustrates NIR images of highly stained occlusal tooth surfaces taken using light of 1250nm wavelength. The absorption by stain is minimal;

Figure 7 illustrates apparatus including a hand-held intra-oral probe and remote computing components.

In the figures like items are assigned like reference symbols for consistency.

Figure 1 illustrates schematically an apparatus 1 for imaging a tooth.

The apparatus includes an intra-oral hand-held probe 2 dimensioned to be held in the hand of a user and at least partly inserted into the mouth of a patient immediately adjacent a target tooth.

The apparatus includes an infra-red camera 19 and an illumination light source 3 each remote from the probe 2 and each in optical communication with the probe 2 via a respective one of two aligned optical fibre bundles (4, 5). The illumination light means is arranged to generate light of a broadband spectral content covering visible light and near-infra-red light (e.g. including wavelengths in a range from 300nm to 2500nm or more, preferably inclusive of all such wavelengths), and to output generated light to an input end 4A of a first of the two aligned optical fibre bundles 4 for

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transmission therealong to an output end 4B thereof housed in the probe 2 for output from the probe in illuminating a target tooth 25.

Preferably, the illumination light source 3 and the optical fibre bundles 4,5 are arranged to deliver full-field illumination to the target tooth 25. The infra-red camera 19 is likewise arranged to detect or capture full-field images. That is, the apparatus works on a full-field principle in which a whole area of the target tooth 25 is illuminated and a corresponding image captured, rather than scanning a point-like illumination across the surface of the tooth.

The infra-red camera 19 contains an infra-red pixel sensor array (not shown) responsive to infra-red radiation incident upon in to generate one or more image pixel values, and to output the pixel value(s) for use. A second of the two aligned optical fibre bundles 5 places the probe 2 in optical communication with an infra-red camera 19, and possesses an optical input end 5B housed within the probe 2 and arranged to receive light returned from a target tooth 25, and to guide the returned light to an optical output end 5A thereof for receipt by the infra-red pixel sensor array of the infra-red camera.

Immediately adjacent the optical input end 5B of the second aligned optical fibre bundle 5, and housed within the probe, is one or more input image collecting optical element 6 (e.g. one or more lenses) arranged in optical communication with the optical input end of the second aligned optical fibre bundle. The input image collecting optical element possesses an optical axis co-linear with that of the optical input end of the second aligned optical fibre bundle, and is adapted and arranged, or controllable, to gather light received thereby and to direct the gathered light into the optical input end of the second aligned optical fibre bundle. The image-collecting optical element 6 is arranged and controllable to form a

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focused optical image upon the exposed terminal optical input end 5B of the second aligned optical fibre bundle 5 using returned infra-red light from the target tooth 25. In this way, a focused image of the target tooth 25 may be transmitted along the second aligned optical fibre bundle 5 to the infra-red camera 19. In effect, the second aligned optical fibre bundle 5 serves to optically place the infra-red pixel sensor array of the infra-red camera 19 effectively or notionally within the intra-oral hand-held probe 2, without being physically present there. That is to say, the flat surface collectively formed by the plurality of closely-packed optical fibre ends defining the optical input end 5B of the second aligned optical fibre bundle, acts as a proxy imaging surface.

Indeed, in alternative examples of the invention, such as is schematically illustrated in figure 7, the second aligned optical fibre bundle 5 may be dispensed with and a detachably attachable unit 50 may be provided containing an infra-red camera 19, and additional optical elements e.g. a filter unit 18, imaging optical element(s) 17, illumination light source 3, and aligned optical fibre bundle 4 for guiding light generated by the illumination means outwardly of the detachable unit 50. The detachable unit 50 may include an optical window 35 with which the imaging optical element(s) 17, the filter unit 18, the infra-red camera 19, the illumination light source 3 and the first aligned optical fibre bundle 4 are in optical communication to enable light from the illumination light source 3 to exit the detachable unit 50, and to allow returned light to pass into the detachable unit 50 through the optical elements, the filter unit, and to the infra-red camera therein. In this alternative example, a second optical window 30 is provided at a surface of the hand-held probe 2 positioned relative to a plurality of positioning lugs 40 arranged and dimensioned to intimately receive the detachable unit at that part thereof containing the input/output window 35 thereof. The lugs 40 may be arranged to enable a snap-fit connection or a screw-fit

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connection or any other suitable connection as may be desirable. The dimensioning of the relevant receivable part of the detachable unit 50 and the receiving lugs 40 is such as to align, in register, the input/output window 35 of a detachable unit 50 with the input/output window 30 of the hand-held probe 2. This enables optical communication between the optical elements within the detachable probe and associated optical elements within the hand-held probe. Reference numerals employed in figure 7 identify the same articles as described with reference to figure 1 herein.

Adjacent the input image collecting optical element 6, and in optical communication therewith, is an input optical linear polarising filter 8 arranged to receive light returned from an illuminated target tooth 25 and to transmit substantially only that part of the received light which is linearly polarised light according to the polarisation axis defined by the filter, for transmission through the input image collecting optical element 6 and along the second aligned optical fibre bundle 5 for receipt by the infra-red camera 19.

The first aligned optical fibre bundle 4 comprises a group of optically aligned (i.e. with parallel optical axes) optical fibres which collectively envelop the second aligned optical fibre bundle 5 thereby forming therearound, in cross-section, a ring or annulus of optical fibres.

The optical input end 4A of the first aligned optical fibre bundle adjacent the illumination light source 3, is spaced from the second aligned optical fibre bundle 5 by a diversion or bifurcation of the optical fibres of the first aligned bundle from those of the second aligned optical fibre bundle, at a location between the probe 2 and the infra-red camera 19. This permits the illumination light source 3 to be located at any convenient location separated from the optical output end 5A of the second aligned optical fibre bundle 5 and any elements of the apparatus following that (e.g. IR camera 19).

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The optical output end 4B of each optical fibre of the first aligned optical fibre bundle 4, housed within the probe 2, is in immediate optical communication with an output optical linear polarising filter 7 arranged to receive light guided from the illumination light source 3 along the first aligned fibre bundle 4, and to transmit light linearly polarised according to the linear polarisation axis of the output optical linear polarising filter for illuminating a target tooth 25.

The linear polarisation axis of the output optical linear polarising filter 7 is aligned to be perpendicular to the axis of linear polarisation of the input optical linear polarising filter 8. This reduces the content, within light returned to the probe from an illuminated tooth 25, of light resulting from specular reflection from a surface of the illuminated tooth. Polarised light transmitted by the output optical linear polarising filter, specularly reflected from a tooth surface, tends to preserve its initial state of polarisation. Consequently, such preserved polarisation prevents transmission of such light through the input optical linear polarising filter thereby at least to some extend eliminating specularly reflected light which has not undergone de-polarisation by scattering within the material (e.g. enamel) of the target tooth.

A beam-splitting mirror 9 is arranged in optical communication with both the optical output end 4B of the first aligned optical fibre bundle and the optical input end 5B of the second aligned optical fibre bundle so as to receive light output by the output linear optical polarising filter 7 and to reflect such received light through an angle (e.g. 90°) to direct the light outwardly of the probe 2 via a transparent protective window 10 of the probe. The beam-splitting mirror 9 is also arranged to receive via the protective window 10 light returned from the target tooth 25 and to reflect a

portion of the returned light towards the input optical linear polariser 8 for subsequent transmission to the infra-red camera 19. The beam-splitting mirror 9 is arranged to transmit at least a portion of the visible light (e.g. between 25% and 50%) returned from the tooth 25 such that the light transmitted thereby is received by a reference imaging camera 11 responsive thereto to form an image of the target tooth using optically visible light.

The reference imaging camera preferably comprises a colour camera including a pixel-sensor imaging array 12 responsive to visible light to generate image pixel values for use in generating an image. The reference imaging camera includes an optical filter 14 located between the beam-splitting mirror 9 and the pixel-sensor array 12 and arranged to transmit wavelengths of light corresponding to visible light for receipt by the pixel-sensor array. Located between the filter 14 and the pixel-sensor array 12 is an imaging optical element 13, or optical train, comprising lenses or the like arranged to form an image on the pixel-sensor array 12 using light transmitted thereto by the filter 14. The imaging optical element 13 is preferably adapted for forming images over the whole visible light spectrum and the pixel-sensor array 12 is preferably a colour pixel-sensor array adapted to form colour images.

A control panel 15 is arranged upon the probe and comprises one or more control buttons, or other manually operable control user-interfaces (not shown), enabling the user to control functions and operations of the probe by hand.

The control panel may be arranged to control any one or more of: the capturing of images by the reference camera 11 (e.g. act as a "shoot" button); the capturing of images by the IR camera unit 19; the intensity of illuminating light produced by the illumination light source 3; the filtering state of the filter unit 18; the focussing of the image collecting optics

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6; the optical magnification provided by (e.g. zoom) the image collecting optics 6.

A remote imaging optical element(s) 17 and a filter unit 18 are arranged in successive common optical communication with, and between, the optical output end 5A of the second aligned optical fibre bundle 5, distal the probe 2, and the infra-red imaging camera 19.

The remote imaging optical element(s) 17 comprises one or more lens elements, or the like, arranged to form from light received thereby from the second aligned optical fibre bundle 5 an image of the target tooth 25 from which the light in question was returned.

The filter unit 18 is arranged to receive light output by the remote imaging optical element(s) 17 and to transmit, according to the optical transmission characteristics of the filter unit, portions of received light to the infra-red pixel sensor array of the infra-red camera 19. The remote imaging optical element(s) 17 may be arranged or controllable for form a focused image on the infra-red pixel sensor array via the filtering optics of the filter unit 18. The filter unit may comprise a liquid-crystal variable optical filter element possessing a selectively variable optical transmission spectral characteristic and being controllable to selectively transmit optical radiation only within any one of a number of selected wavelength bandwidths (e.g. infra-red radiation). Alternatively, the filter unit 18 may comprise a filter wheel including a plurality of separate dedicated filter elements (e.g. glass filters of the like) each possessing a fixed spectral transmission characteristic and each being selectively movable into the path of light output by the imaging optics 17 thereby to filter that light for subsequent transmission to the infra-red camera 19.

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The filtering unit is arranged to selectively filter light received thereby according to any selected one of three pass-band transmission spectral characteristics with each pass-band preferably centred upon a respective desired wavelength value (e.g. a value selected from: 1090nm, 1440nm, 1610nm).

A first pass band of the filtering unit may be a pass band which extends from 1300nm to 1550nm, or from 1400nm to 1500nm, and may be centred on 1440nm. A second pass band may extend from 1550nm to 1800nm, or from 1550nm to 1650nm, and may be centred on 1610nm. A reference pass band of the filtering unit may be a pass band which extends from 1000nm to 1150nm, or from 1050nm to 1130nm, and may be centred upon 1090nm. A third pass band of the filtering unit may be a pass band which extends from 1850nm to 1970nm, or from 1880nm to 1940nm, and may be centred upon 1910nm. The pass band width of any one or more, or each, of the filter pass bands is preferably from 10nm to 15nm in extent. However, the pass band width in question may be up to 60nm in extent, or thereabouts. The pass band width in question may be any size less than 60nm and preferably wholly falls within a range of wavelengths which is 60nm in extent and is centred upon a value selected from: 1090nm, 1440nm, 1610nm.

Accordingly, operation of the filtering unit enables the infra-red camera to generate image pixel values representative of a respective one of three different images formed using light of a corresponding one of three different infra-red wavelengths. Reflectance values may be calculated from two of the three images using pixel values of the third image to normalise the reflectance values. Reflectance values may be used to calculate a measure of lesion (e.g. a carries score) a given imaged part of the tooth common to all three images.

The apparatus further includes a computer 20, such as a personal computer or the like, arranged to receive image pixel values representative of images formed upon the infra-red

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pixel sensor array of the infra-red camera 19, and to process those pixel values as discussed below.

The illumination source 3, the control panel 15 of the probe 2, and the reference imaging camera 11 of the probe 2, are each also in communication with the computer 20 via a data transmission link 16 via which control data and image data are passed between the elements of the apparatus interconnected thereby.

A control foot switch 21 is connected in operable communication with the computer 20 and is arranged to control any one or more of: the capturing of images by the reference camera 11 (e.g. act as a "shoot" button); the capturing of images by the IR camera unit 19; the intensity of illuminating light produced by the illumination light source 3; the filtering state of the filter unit 18; the focussing of the image collecting optics 6; the optical magnification provided by (e.g. zoom) the image collecting optics 6. The implementation of these functions via the control foot switch enables a user to control the operation of the probe 2 without having to manually operate elements of the control panel 15 when it is desirable not to move or shake the probe - such as when "shooting" images in use or the like.

The computer includes image processing means (e.g. implemented using software) arranged to receive pixel image values from the infra-red camera and to produce images therefrom. The image processing means is arranged to co-register separately acquired images of a common target tooth 25, each obtained using a different selected respective filter of the filter unit, thereby to associate a given image pixel of the any one co-registered image with a respective image pixel of any other co-registered image representing the same part of the imaged subject. This a reflectance spectrum or profile to be generated in respect of each such co-registered pixel value, thereby providing a hyper-spectral image data set to be

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formed. The reference image pixel values generated by the reference camera 11 are also received by the computer (via data transmission line 16) and are co-registered with images containing the same target tooth 25 via the IR camera 19 at different IR wavelengths. Thus, a "visible light" reference image may be provided representing the imaged tooth as would be perceived by the user regarding the tooth, together with two or three corresponding (and co-registered) images of the target tooth taken using one of two or three different infra-red (IR) wavelengths of light. The image processing means preferably permits the user to select upon the reference image of the tooth a pixel representing a given location on the tooth, and in response to such selection may present and one or more of: the pixel values of the corresponding IR images co-registered with the reference image corresponding to the selected location on the tooth; reflectance values of the selected location in respect of the wavelengths of light employed to generate the IR images; a measure of lesion present in the tooth at the selected region of the tooth; a carries score in respect of the selected region of the tooth.

In one example, the computer includes data processing means is arranged, in respect of a given part of the imaged tooth, to use one or more image pixel values of a first IR image (taken using a first IR wavelength or pass-band) to calculate a first reflectance value associated with the part, and to use one or more image pixel values of a second IR image (taken using a second IR wavelength or pass-band different from the first) to calculate a second reflectance value associated with the same tooth part. The data processing means of the computer determines from the first and second reflectance values a measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the common tooth part. An example is given below.

The data processing means may be arranged to use this measure of the degree of enamel lesion (S_e) and the measure of the

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degree of dentin lesion (S_d) to calculate a measure (S_{caries}) of the degree of caries present in the part. An example is given below.

Well defined signatures have been observed in reflectance (R) spectra from teeth at NIR wavelengths. Reflectance (R) above 1400nm tend to be higher for the decayed areas and in particular at 1610nm. NIR reflectance dips (i.e. NIR absorption) are pronounced by dentin lesion, and especially at 1440nm.

A first pass band of the filtering unit may be a pass band which extends from 1300nm to 1550nm, or from 1400nm to 1500nm, and may be centred on 1440nm. A second pass band may extend from 1550nm to 1800nm, or from 1550nm to 1650nm, and may be centred on 1610nm. A reference pass band of the filtering unit may be a pass band which extends from 1000nm to 1150nm, or from 1050nm to 1130nm, and may be centred upon 1090nm. A third pass band of the filtering unit may be a pass band which extends from 1850nm to 1970nm, or from 1880nm to 1940nm, and may be centred upon 1910nm. The pass band width of any one or more, or each, of the filter pass bands is preferably from 10nm to 15nm in extent. However, the pass band width in question may be up to 60nm in extent, or thereabouts. The pass band width in question may be any size less than 60nm and preferably wholly falls within a range of wavelengths which is 60nm in extent and is centred upon a value selected from: 1090nm, 1440nm, 1610nm, 1910nm.

The computer 20 is arranged to process pixel values (correlated to spectral intensity) at each IR image pixel by normalising it to (e.g. dividing it by) the corresponding (co-registered) image pixel value associated with a reference reflectance (R) e.g. obtained at the wavelength with the highest reflectance (least extinction) e.g. 1090nm. The degree of enamel, S_e, and dentin, S_d, lesions are to be calculated by the computer as follows:

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$$S_e = S_e^{(1)} = \frac{R(1610nm)}{R(1090nm)} \quad \text{or} \quad S_e = S_e^{(1)} = \frac{R(1440nm) - R(1910nm)}{R(1090nm)}$$

$$S_d = \frac{R(1610nm) - R(1440nm)}{R(1090nm)}$$

As can be seen from figure 3, a rise in reflectance occurs at around 1900nm and is associated with the scattering of infra-red light from demineralised tooth enamel. In demineralised enamel, light is scattered more than in sound enamel. Scattered intensity is typically a function of wavelength, that is to say, the amount of light scattered tends to drop in inverse proportion to wavelength increases. In a non-absorbing medium the wavelength dependence becomes apparent when comparing the reflectance intensities of two spectral regions. In such a case, demineralised enamel presents a scattering characteristic in the spectral reflectance thereof. The degree of enamel lesion $S_e^{(2)}$ is suitable for use to enhance the effect of scattering of light and to separate the influence of absorption by water. Two spectral dips occur in the spectrum of figure 3 at about 1440nm and 1910nm, and a comparison of the reflectance intensities at these wavelengths is employed. By looking at the intensity of these two dips, when scattering dominates over water absorption, the dips may become less pronounced, but the wavelength dependence introduced by scattering will become stronger. In this way, the relative rise in reflectance at 1910nm is principally due to enamel demineralisation, and the relationship between the two spectral intensities employed in the measure $S_e^{(2)}$ is used to unveil this feature.

The computer is arranged to calculate the caries score, S_{caries}, as follows:

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$$S_{caries} = p\left(\frac{S_e - K_e}{N_e}\right) + (1-p)\left(1 + \frac{S_d - K_d}{N_d}\right)$$

Here, K_x and N_x are the enamel (x : e) and dentin (x : d) score calibration offset and normalisation factor, respectively. In addition, $p = 1$ if

$$\left(1 + \frac{S_d - K_d}{N_d}\right) \prec S_{dth}$$

where S_{dth} represents the dentin lesion threshold, otherwise $p = 0$.

An example of another implementation of the invention follows using sample target teeth.

Twelve extracted human teeth (premolars and molars) with natural lesions of various degrees were acquired. Soft tissues were removed from the collected teeth and these were thoroughly cleaned. Each tooth was stored in a separate container with distilled water and 0.5% thymol to keep them hydrated and sterile and therefore free from bacteria. Note that the teeth were kept for at least 2 hours in the bottle containers before any (hyperspectral) images were taken to get the measurements closer to the natural hydration conditions. The excess of water on the occlusal surfaces was however gently wiped off using cotton.

A near-infrared (NIR) hyperspectral camera was used to capture the spectral reflectance from the samples. The instrument images a line of vision at a time and diffracts the light onto a 2-dimensional pixel-sensor array by means of a diffraction grating. A complete stack of spectral images (spectral data cube) is obtained by translating the sample at constant speed and line-imaging synchronously. The spectral analysis range was from 1000 nm to 2500 nm with a spectral resolution of 10 nm. Figure 1 shows an image of the system set-up. Note that a

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two-side illumination using halogen lamps was configured to reduce the effect of shadowing.

Acquired reflectance data, a dark current measurement associated with the data acquired (for noise subtraction), reflectance spectra of a reference object and its associated dark current measurement were used as follows to calibrate spectral reflectance data, this calculation being performed for each image pixel value:

$$R(\lambda) = \frac{R_r(\lambda) - D_r}{W_{ref}(\lambda) - D_w} W_{spec}(\lambda) \qquad \text{eq. (1)}$$

Here $R(\lambda)$, $R_r(\lambda)$ and $W_{ref}(\lambda)$ are the calibrated, raw and white reference measurements at wavelength λ, respectively. $W_{spec}(\lambda)$ corresponds to a white reference reflectance at wavelength λ. In addition, D_r and D_w are the dark current noise measurements obtained for the raw white reference reflectance data.

Histological information was obtained for all samples after obtaining the NIR hyperspectral images. The teeth were grounded along the transversal plane to their surface. Sub-millimetres grounding steps were performed and a photograph was taken after each step. The histology scoring was done for the slide showing the most representative lesion for each tooth. The score was given based on the criteria shown in Table I.

TABLE I: Histology scoring criteria.

Score	Code: Lesion depth
0	S : Sound
1	E1 : 1/3 enamel
2	E2 : 2/3 enamel
3	EDJ: enamel-dentin junction
4	D1 : 1/3 dentin
5	D2 : 2/3 dentin

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6	D3 : to the pulp

As an example, a selection of the spectral images obtained from an occlusal tooth surface is shown in Figure 2 at the wavelengths indicated. It is possible to see that the reflectance intensity drops at higher wavelengths.

A typical reflectance spectrum for sound material, white spot material (enamel lesion) and a dentin lesion material is shown in Figure 3. Well defined signatures can be observed among the three cases. For instance, reflectance above 1400nm is clearly higher for the decayed areas and in particular at 1610nm. However, the absorption dips are further pronounced for the case of dentin lesion, and specially at 1440nm.

The spectral intensity at each pixel was normalised to the reflectance obtained at 1090 nm since this the wavelength with the highest reflectance (least extinction). The degree of enamel, S_e, and dentin, S_d, lesions were therefore calculated as follows:

$$S_e = \frac{R(1610nm)}{R(1090)} \qquad \text{eq. (2)}$$

$$S_d = \frac{R(1610nm) - R(1440nm)}{R(1090)} \qquad \text{eq. (3)}$$

A caries score, S_{caries}, was calculated as a combination of S_e and S_d and was designed to account for the deepest lesion observed by the NIR spectrum as follows:

$$S_{caries} = p\left(\frac{S_e - K_e}{N_e}\right) + (1-p)\left(1 + \frac{S_d - K_d}{N_d}\right) \qquad \text{eq. (4)}$$

Here, K_x and N_x are the enamel (x : e) and dentin (x : d) score calibration offset and normalisation factor, respectively. In addition, p = 1 if

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$$\left(1+\frac{S_d-K_d}{N_d}\right) \prec S_{dth}$$

where S_{dth} represents the dentin lesion threshold, otherwise p = 0.

Outliers and noise introduced by specular reflections were removed by limiting the values of the numerators in Equation 4 to the range $0 < (S_e - K_e) < M_e$ and $0 < (S_d - K_d) < M_d$; here M_e and M_d denote the upper limits. Values outside these limits were set to zero.

In order to fix the range of S_{caries} from 0 to 2, the normalization factors in Equation 4 were expressed as $N_e = M_e/S_{dth}$ and $N_d = M_d$. Therefore for values in the range of $0 < S_{caries} \leq S_{dth}$ the score indicates an enamel lesion and for $S_{caries} > S_{dth}$ the score indicates a dentin lesion. Note that sound areas have a value of $S_{caries} = 0$.

The calibration values for the equations above were obtained empirically. For our case, results were best described with $S_{dth} = 1.1$, $K_e = 0.14$, $K_d = 0.05$, $M_e = 0.35$, and $M_e = 0.15$.

Twelve teeth with different lesion degrees were imaged and processed following the method described above. As an example, coded S_{caries} maps for four teeth are shown in Figure 4. The associated pictures and the selected histological sections chosen are also shown.

Note that the extension of the lesion is not evident from the pictures in Figure 4 (which rely on visible wavelengths). It is possible to see however that the caries score maps clearly depict the lesion spatial distribution. This is due to the longer light penetration of NIR wavelengths through enamel. In addition, the depth of the lesions can be confirmed from the histological sections. The arrows pointing toward the colour pictures of Figure 4 indicate the point of view of the

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histological section, which is indicated by the straight line traversing a given picture of a tooth.

For the examples presented in Figure 4, lesions in Tooth A rest within the enamel, having $S_{caries} < 1.1$, whereas the lesions in Teeth B, C and D reach the dentin, having $S_{caries} > 1.1$. These observations can be confirmed with the histological sections which are scored as EDJ for Tooth A and D2 for Teeth B, C and D. The black points highlighted in each carries score map image (by an arrow) correspond to the maximum scores found within the region corresponding to the histological section and the average value is indicated by the arrow.

Hidden lesions, such as the one in Tooth D, are of particular interest since visual inspection does not reveal them easily and they could be left untreated increasing the risk of tooth loss. It is clear from the histology section that the damage has reached the dentin for this case and this is adequately indicated by values of $S_{caries} > 1.1$ around the decayed region.

Detection of caries in pits and fissures is of great interest among the dental practitioners since demineralisation commonly starts in these sites and the detection of them is not always obvious, especially in the presence of stain. The decay in the fissure pattern of Tooth A can be easily discriminated in the S_{caries} map; the demineralised part of the "U"-shaped fissure of this tooth is well described and confirmed with the histological section. Enamel demineralisation in the fissure pattern of the remaining teeth shown in Figure 4 are also depicted by their corresponding S_{caries} map but it is the deepest tooth lesion the one considered for our statistical analysis below.

The NIR images are to some extent affected by specular reflection, especially around the edges and the crests of the teeth where reflections are expected to be strong. These reflections act as a noise factor, especially for the

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calculation of S_e in Equation 2 above. Note that the stain and pigmentation in all teeth did not show a significant interference with the measurements.

The NIR image processing algorithm discriminates well between sound enamel, enamel lesions and dentin lesions.

A region from each of the S_{caries} maps corresponding to the selected histological section was obtained. A histogram of the values obtained across this region was calculated and the value corresponding to the highest bin with more than five pixels was extracted. This reduces or removes false maxima that could be caused by specular reflections. The average of the values within the extracted bin was used as an indication of the maximum S_{caries} score in the region and was compared to the histology score.

Figure 5 shows a correlation graph between the two scores and a Pearson correlation 0.89 significant at a level $p < 0.01$ was found. In addition, a sensitivity of 75% and a specificity of 87.5% for enamel lesions and a sensitivity of 87.5% and a specificity of 100% for dentine lesions were found using the NIR spectral imaging method.

Detecting early stages of tooth decay is advantageous as it is reversible and the progression to a stage where restorative intervention is required might therefore be avoided. Screening early lesions in occlusal pits and fissures is advantageous since these regions have a higher susceptibility to bacterial deposition and therefore deminaralisation. Visual inspection and radiography are commonly used in the clinic to perform this task; however, such methods lack the sensitivity needed to detect early stages of the disease and also the ability to quantify its progression.

Hyperspectral imaging is a powerful method used to interrogate the spectral characteristics of samples in a two-dimensional

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space. This is now found to be of particular use when studying teeth due to their inherent heterogeneous occlusal geometry and associated lesion distribution. This method may be employed according to the present invention which demonstrates the ability of NIR spectral imaging to quantify caries lesions from occlusal surfaces. A light reflectance configuration, preferably back-scattering of light, is preferably employed in the invention since uniform illumination of the tooth is easily achieved. Imaging with NIR wavelengths means that stain no longer represents a strong confounding factor when detecting tooth demineralization.

Figure 6 shows an example of the reflectance obtained at a wavelength of 1250 nm for three heavily stained teeth. It is possible to observe that the absorption of light by stain is minimal and confirms previous reported observations employing NIR wavelengths.

Note that the spectral intensity dips observed in the reflectance spectra shown in Figure 3 correspond to the absorption peaks of water. In addition, the expected raise in light scattering caused by white spot lesions can be observed in the spectra as a background intensity across all wavelengths. The results obtained for the different lesions suggest that, as the cavity reaches the dentin, the lesion size increases and the amount of water within increases too. For early enamel demineralization, the effect is rather observed as an augmented light scattered intensity at the surface due to the porous structure of the lesion. These physical effects may be used, according to the invention, as a mechanism to quantify the extension of tooth decay. Use of the reflectance at 1440 nm and 1610 nm, such as presented in Equation 4, is suitable (though other wavelengths may be considered) since these wavelengths appear to be most affected by water absorption and scattering as shown in Figure 3 for enamel and dentin lesions. Sound regions of the teeth show a reduced reflectance at wavelengths above 1450 nm; this may be

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caused by an increase in the absorption of light by hydroxyapatite and/or collagen; decayed areas have a reduced amount of mineral and/or organic material and this may explain the observed higher reflectance at such wavelengths.

Although special attention may be paid in pixel data processing algorithms discussed above, to remove the influence of specular reflections from reflectance data, measured pixel data values may still be affected by this source of noise, in particular at the edges and crests of the tooth present strong reflections are expected.

In another example, the filtering unit is arranged to selectively filter light received thereby according to any selected one of four pass-band transmission spectral characteristics with each pass-band preferably centred upon a respective desired wavelength value (e.g. a value selected from: 1090nm, 1440nm, 1610nm, 1910nm).

The above examples are intended for illustration and are not intended to be limiting. Variants and modifications to the examples, such as would be readily apparent to the skilled person, may be made without departing from the scope of the invention.

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The following statements provide general expressions of the disclosure herein.

A. Apparatus for imaging a tooth including:

illumination means arranged to generate first infra-red light with a first wavelength having a value within a range of values corresponding to an infra-red spectral absorption band of water, to generate second infra-red light with a second wavelength having a value within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel, and for illuminating a tooth therewith;

image data acquisition means arranged for receiving infra-red light originating from the illumination means and returned from an illuminated tooth, and including infra-red pixel sensor means responsive to said returned infra-red light to generate image pixel values for a first image of the illuminated tooth using first infra-red light and not second infra-red light and to generate image pixel values for a second image of the illuminated tooth using second infra-red light and not first infra-red light, and to provide such image pixel values for use.

B. Apparatus according to any preceding statement in which the image data acquisition means includes optical input means via which the apparatus is arranged to receive infra-red light returned from an illuminated tooth in a direction substantially parallel with, or subtending an acute angle with respect to, a direction of illumination by the illumination means.

C. Apparatus according to any preceding statement in which the illumination means comprises optical output means with an optical axis along which the apparatus is arranged to output said infrared light to illuminate a tooth, and the image data acquisition means includes optical input means comprising an optical axis along which the apparatus is arranged to receive

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infrared light returned from an illuminated tooth and which is substantially parallel to, or subtends an acute angle with respect to, the optical axis of the illumination means.

D. Apparatus according to any preceding statement in which the image data acquisition means includes camera means including a pixel sensor array responsive to visible light returned from an illuminated tooth to form one or more image pixel values representing an image of at least a part of the tooth.

E. Apparatus according to any preceding statement including infra-red optical filter means selectively operable in a first state to transmit infra-red light originating from the illumination means having said first wavelength and to substantially prevent transmission therethrough of infra-red light having said second wavelength, and in a second state to transmit infra-red light originating from the illumination means having said second wavelength and to substantially prevent transmission therethrough of infra-red light having said first wavelength.

F. Apparatus according to statement E in which the infra-red optical filter means is arranged in optical communication with the infra-red pixel sensor means to filter infra-red light directed to the infra-red pixel sensor means by the image data acquisition means.

G. Apparatus according to statement E in which the illumination means comprises light-source means operable to generate light including said first and second wavelengths, wherein the infra-red optical filter means is arranged in optical communication with the light-source means to filter light generated by the light-source means for illuminating a tooth with infra-red radiation transmitted by the infra-red optical filter means.

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H. Apparatus according to any preceding statement in which the illumination means comprises light-source means operable to generate light including said first and second wavelengths, and optical output means remotely in optical communication with the light-source means via output optical waveguide means and arranged to output from the apparatus light generated by the light-source means to illuminate a tooth.

I. Apparatus according to any preceding statement including optical input means remotely in optical communication with the infra-red pixel sensor means via input optical waveguide means and arranged to receive infra-red light returned from an illuminated tooth and to direct the returned infra-red light to the remote infra-red pixel sensor means for sensing thereby.

J. Apparatus according to statement H and statement I including a remote intra-oral probe comprising the optical input means and the optical output means.

K. Apparatus according to statement J in which the input optical waveguide means comprises one or more optical fibres which collectively define an aligned optical fibre bundle.

L. Apparatus according to statement J or K in which the output optical waveguide means comprises one or more optical fibres collectively defining an aligned optical bundle.

M. Apparatus according to statements J to L in which at least a terminal end of the output optical waveguide means is adjacent the optical input means.

N. Apparatus according to statement M in which the terminal end of the output optical waveguide comprises a bundle of optical fibres the ends of which form a ring circumscribing the output optical waveguide.

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O. Apparatus according to any preceding statement in which the illumination means comprises first optical polarizer means for polarizing according to a first polarization axis infra-red radiation generated by the illumination means, and the image data acquisition means comprises second optical polarizer means for polarizing according to a second polarization axis transverse to the first polarization axis infra-red radiation received thereby from an illuminated tooth.

P. Apparatus according to any preceding statement in which the image data acquisition means comprises focussing means arranged to form upon the infra-red pixel sensor means a real optical image using infra-red light received by the image data acquisition means from an illuminated tooth.

Q. Apparatus according to statement P when dependent upon statement E and statement I in which the optical filter means, the focussing means and infra-red pixel sensor means are each in mutual optical communication and remotely in optical communication with the optical input means via said input optical waveguide means.

R. Apparatus according to any preceding statement including image processing means arranged to receive said pixel image values for producing one or more of said first and second images therefrom.

S. Apparatus according to statement R in which the image processing means is arranged to co-register a said first image and a said second image in respect of a common imaged subject, thereby to associate a given image pixel of the first image with a respective image pixel of the second image representing the same part of the imaged subject.

T. Apparatus according to any preceding statement including data processing means arranged in respect of a given part of

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the imaged subject to use one or more image pixel values of the first image to calculate a first reflectance value associated with the part, and to use one or more image pixel values of the second image to calculate a second reflectance value associated with the part, and to determine from the first and second reflectance values a measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part.

U. Apparatus according to statement T in which the data processing means is arranged to use said measure of the degree of enamel lesion (S_e) and said measure of the degree of dentin lesion (S_d) to calculate a measure (S_{caries}) of the degree of caries present in the part.

V. Apparatus according to any preceding statement in which the infra-red pixel sensor means is responsive to said returned infra-red light to generate image pixel values for a reference image of the illuminated tooth using reference infra-red light and not first infra-red light nor second infra-red light, and to provide such image pixel values for use.

W. Apparatus according to statements E and V at least in which the infra-red optical filter means is selectively operable in a third state to transmit infra-red light originating from the illumination means having said reference wavelength and to substantially prevent transmission therethrough of infra-red light having any of said first wavelength and said second wavelength.

X. Apparatus according to statement T and statement V or statement W in which the data processor means is arranged to use one or more image pixel values of the reference image to calculate a reference reflectance value associated with the part, and to determine the measure of the degree of enamel

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lesion (S_e) and/or dentin lesion (S_d) present in the part using the reference reflectance value.

Y. Apparatus according to any preceding statement in which the first wavelength value is between 1300nm and 1550nm, and the second wavelength value is between 1550nm and 1800nm.

Z. Apparatus according to statement Y in which the first wavelength value is between 1400nm and 1500nm, such as 1440nm, and the second wavelength value is between 1550nm and 1650nm, such as 1610nm.

ZA. A method for imaging a tooth including:

generating first infra-red light with a first wavelength having a value within a range of values corresponding to an infra-red spectral absorption band of water, generating second infra-red light with a second wavelength having a value within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel, and illuminating a tooth therewith;

receiving at infra-red pixel sensor means first and second infra-red light returned from an illuminated tooth and therewith generating image pixel values for a first image of the illuminated tooth using first infra-red light and not second infra-red light and generating image pixel values for a second image of the illuminated tooth using second infra-red light and not first infra-red light, and providing such image pixel values for use.

ZB. A method according to statement ZA including receiving infra-red light returned from an illuminated tooth in a direction substantially parallel with, or subtending an acute angle with respect to, a direction of said illumination.

ZC. A method according to any of statements ZA to ZB including providing optical output means comprising an optical

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axis and therealong outputting said infrared light to illuminate a tooth, and providing optical input means comprising an optical axis and therealong receiving infrared light returned from an illuminated tooth for subsequent receipt at the infra-red pixel sensor means wherein the said optical axes are substantially parallel, or subtend an acute angle with respect to each other.

ZD. A method according to any of statements ZA to ZC including forming an image representing at least a part of the illuminated tooth using visible light returned therefrom.

ZE. A method according to any of statements ZA to ZD including generating light for illuminating the tooth and in a first instance, filtering the light by transmitting through a filter means parts of said light having said first wavelength and substantially preventing transmission through the filter means of parts of said light having said second wavelength; and in a second instance, filtering the light by transmitting through the filter means parts of said light having said second wavelength and substantially preventing transmission through the filter means parts of said light having said first wavelength.

ZF. A method according to statement ZE including performing said filtering on light directed to the infra-red pixel sensor means.

ZG. A method according to statement ZE including performing said filtering on light for illuminating a tooth.

ZH. A method according to any of statements ZA to ZG including generating said light remotely from said tooth, guiding the generating light to the proximity of the tooth, and illuminating the tooth with the guided light.

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ZI. A method according to any of statements ZA to ZH including guiding said returned infra-red light to a location remote from the point of receipt of the returned light and generating image pixel values using said returned, guided light at said remote location.

ZJ. A method according to any of statements ZA to ZI performed using an intra-oral probe.

ZK. A method according to any of statements ZA to ZJ including polarizing according to a first polarization axis infra-red radiation generated for illuminating a tooth, and polarizing according to a second polarization axis transverse to the first polarization axis infra-red radiation returned from the illuminated tooth.

ZL. A method according to any of statements ZA to ZK including forming upon an infra-red pixel sensor means a real optical image using said infra-red light returned from an illuminated tooth.

ZM. A method according to any of statements ZA to ZL including producing one or more of said first and second images from said returned light.

ZN. A method according to statement ZM including co-registering a said first image and a said second image in respect of a common imaged subject, thereby to associate a given image pixel of the first image with a respective image pixel of the second image representing the same part of the imaged subject.

ZO. A method according to any of statements ZA to ZN including generating image pixel values for a reference image of the illuminated tooth using reference infra-red light returned from the tooth and not first infra-red light nor

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second infra-red light, and providing such image pixel values for use.

ZP. A method according to statement ZO including, in respect of a given part of the imaged subject, calculating a first reflectance value R_1 associated with the part using one or more image pixel values of the first image, calculating a second reflectance value R_2 associated with the part using one or more image pixel values of the second image, calculating a reference reflectance value R_{ref} associated with the part using one or more image pixel values of the third image and determining from the first, second and reference reflectance values the values of the ratios R_1/R_{ref} and R_2/R_{ref} and providing the ratio values for use.

ZQ. A method according to statement ZP including calculating a value $(R_2/R_{ref}-R_1/R_{ref})$ and providing the value for use.

ZR. A method according to any of statements ZA to ZQ including generating light for illuminating the tooth and in a third instance, filtering the light by transmitting through a filter means parts of said light having said reference wavelength and substantially preventing transmission through the filter means of parts of said light having any of said first wavelength and said second wavelength.

ZS. A method according to any of statements ZA to ZR in which the first wavelength value is between 1300nm and 1550nm, and the second wavelength value is between 1550nm and 1800nm.

ZT. A method according to statement ZS in which the first wavelength value is between 1400nm and 1500nm, such as 1440nm, and the second wavelength value is between 1550nm and 1650nm, such as 1610nm.

ZU. A computer programmed to implement the method of any of statements ZM to ZQ.

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ZV. A computer program product comprising a computer-readable medium containing computer executable instructions which implement the method of any of statements ZM to ZQ when executed on a computer.

ZW. A computer program containing computer executable instructions which implement the method of any of statements ZM to ZQ when executed on a computer.

ZX. Apparatus according to any of statements A to Z including computer means programmed for use in implementing the method of any of statements ZA to ZT.

ZY. A computer program product comprising a computer-readable medium containing computer executable instructions for use in implementing the method of any of statements ZA to ZT when executed on apparatus according to statement ZX.

ZZ. A computer program containing computer executable instructions which implement the method of any of statements ZA to ZT when executed on apparatus according to statement ZX.

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CLAIMS:

1. Apparatus for imaging a tooth including:

illumination means arranged to generate first infra-red light with a first wavelength having a value within a range of values corresponding to an infra-red spectral absorption band of water, to generate second infra-red light with a second wavelength having a value within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel, and for illuminating a tooth therewith;

image data acquisition means arranged for receiving infra-red light originating from the illumination means and returned from an illuminated tooth, and including infra-red pixel sensor means responsive to said returned infra-red light to generate image pixel values for a first image of the illuminated tooth using first infra-red light and not second infra-red light and to generate image pixel values for a second image of the illuminated tooth using second infra-red light and not first infra-red light, and to provide such image pixel values for use; and

data processing means arranged in respect of a given part of the imaged subject to use one or more image pixel values of the first image to calculate a first reflectance value associated with the part, and to use one or more image pixel values of the second image to calculate a second reflectance value associated with the part, and to determine from the first and second reflectance values a measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part.

2. Apparatus according to any preceding claim in which the image data acquisition means includes optical input means via which the apparatus is arranged to receive infra-red light returned from an illuminated tooth in a direction substantially parallel with, or subtending an acute angle with

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respect to, a direction of illumination by the illumination means.

3. Apparatus according to any preceding claim in which the illumination means comprises optical output means with an optical axis along which the apparatus is arranged to output said infrared light to illuminate a tooth, and the image data acquisition means includes optical input means comprising an optical axis along which the apparatus is arranged to receive infrared light returned from an illuminated tooth and which is substantially parallel to, or subtends an acute angle with respect to, the optical axis of the illumination means.

4. Apparatus according to any preceding claim in which the data processing means is arranged to use said measure of the degree of enamel lesion (S_e) and said measure of the degree of dentin lesion (S_d) to calculate a measure (S_{caries}) of the degree of caries present in the part.

5. Apparatus according to any preceding claim in which the image data acquisition means includes camera means including a pixel sensor array responsive to visible light returned from an illuminated tooth to form one or more image pixel values representing an image of at least a part of the tooth.

6. Apparatus according to any preceding claim including infra-red optical filter means selectively operable in a first state to transmit infra-red light originating from the illumination means having said first wavelength and to substantially prevent transmission therethrough of infra-red light having said second wavelength, and in a second state to transmit infra-red light originating from the illumination means having said second wavelength and to substantially prevent transmission therethrough of infra-red light having said first wavelength.

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7. Apparatus according to claim 6 in which the infra-red optical filter means is arranged in optical communication with the infra-red pixel sensor means to filter infra-red light directed to the infra-red pixel sensor means by the image data acquisition means.

8. Apparatus according to claim 7 in which the illumination means comprises light-source means operable to generate light including said first and second wavelengths, wherein the infra-red optical filter means is arranged in optical communication with the light-source means to filter light generated by the light-source means for illuminating a tooth with infra-red radiation transmitted by the infra-red optical filter means.

9. Apparatus according to any preceding claim in which the illumination means comprises light-source means operable to generate light including said first and second wavelengths, and optical output means remotely in optical communication with the light-source means via output optical waveguide means and arranged to output from the apparatus light generated by the light-source means to illuminate a tooth.

10. Apparatus according to any preceding claim including optical input means remotely in optical communication with the infra-red pixel sensor means via input optical waveguide means and arranged to receive infra-red light returned from an illuminated tooth and to direct the returned infra-red light to the remote infra-red pixel sensor means for sensing thereby.

11. Apparatus according to claim 9 and claim 10 including a remote intra-oral probe comprising the optical input means and the optical output means.

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12. Apparatus according to claim 11 in which the input optical waveguide means comprises one or more optical fibres which collectively define an aligned optical fibre bundle.

13. Apparatus according to claim 11 or 12 in which the output optical waveguide means comprises one or more optical fibres collectively defining an aligned optical bundle.

14. Apparatus according to claims 11 to 13 in which at least a terminal end of the output optical waveguide means is adjacent the optical input means.

15. Apparatus according to claim 14 in which the terminal end of the output optical waveguide comprises a bundle of optical fibres the ends of which form a ring circumscribing the output optical waveguide.

16. Apparatus according to any preceding claim in which the illumination means comprises first optical polarizer means for polarizing according to a first polarization axis infra-red radiation generated by the illumination means, and the image data acquisition means comprises second optical polarizer means for polarizing according to a second polarization axis transverse to the first polarization axis infra-red radiation received thereby from an illuminated tooth.

17. Apparatus according to any preceding claim in which the image data acquisition means comprises focussing means arranged to form upon the infra-red pixel sensor means a real optical image using infra-red light received by the image data acquisition means from an illuminated tooth.

18. Apparatus according to claim 17 when dependent upon claim 6 and claim 10 in which the optical filter means, the focussing means and infra-red pixel sensor means are each in mutual optical communication and remotely in optical

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communication with the optical input means via said input optical waveguide means.

19. Apparatus according to any preceding claim including image processing means arranged to receive said pixel image values for producing one or more of said first and second images therefrom.

20. Apparatus according to claim 19 in which the image processing means is arranged to co-register a said first image and a said second image in respect of a common imaged subject, thereby to associate a given image pixel of the first image with a respective image pixel of the second image representing the same part of the imaged subject.

21. Apparatus according to any preceding claim in which the infra-red pixel sensor means is responsive to said returned infra-red light to generate image pixel values for a reference image of the illuminated tooth using reference infra-red light and not first infra-red light nor second infra-red light, and to provide such image pixel values for use.

22. Apparatus according to claims 6 and 21 at least in which the infra-red optical filter means is selectively operable in a third state to transmit infra-red light originating from the illumination means having said reference wavelength and to substantially prevent transmission therethrough of infra-red light having any of said first wavelength and said second wavelength.

23. Apparatus according to claim 21 or claim 22 in which the data processor means is arranged to use one or more image pixel values of the reference image to calculate a reference reflectance value associated with the part, and to determine the measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part using the reference reflectance value.

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24. Apparatus according to any preceding claim in which the first wavelength value is between 1300nm and 1550nm, and the second wavelength value is between 1550nm and 1800nm.

25. Apparatus according to claim 24 in which the first wavelength value is between 1400nm and 1500nm, such as 1440nm, and the second wavelength value is between 1550nm and 1650nm, such as 1610nm.

26. A method for imaging a tooth including:

generating first infra-red light with a first wavelength having a value within a range of values corresponding to an infra-red spectral absorption band of water, generating second infra-red light with a second wavelength having a value within a range of values corresponding to an infra-red spectral reflection band characteristic of scattering from demineralised tooth enamel, and illuminating a tooth therewith;

receiving at infra-red pixel sensor means first and second infra-red light returned from an illuminated tooth and therewith generating image pixel values for a first image of the illuminated tooth using first infra-red light and not second infra-red light and generating image pixel values for a second image of the illuminated tooth using second infra-red light and not first infra-red light, and providing such image pixel values for use; and

in respect of a given part of the imaged subject, calculating a first reflectance value associated with the part using one or more image pixel values of the first image, and calculating a second reflectance value associated with the part using one or more image pixel values of the second image, and determining from the first and second reflectance values a measure of the degree of enamel lesion (S_e) and/or dentin lesion (S_d) present in the part.

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27. A method according to claim 26 including receiving infra-red light returned from an illuminated tooth in a direction substantially parallel with, or subtending an acute angle with respect to, a direction of said illumination.

28. A method according to any of claims 26 to 27 including providing optical output means comprising an optical axis and therealong outputting said infrared light to illuminate a tooth, and providing optical input means comprising an optical axis and therealong receiving infrared light returned from an illuminated tooth for subsequent receipt at the infra-red pixel sensor means wherein the said optical axes are substantially parallel, or subtend an acute angle with respect to each other.

29. A method according to any of claims 26 to 28 including forming an image representing at least a part of the illuminated tooth using visible light returned therefrom.

30. A method according to any of claims 26 to 29 including generating light for illuminating the tooth and in a first instance, filtering the light by transmitting through a filter means parts of said light having said first wavelength and substantially preventing transmission through the filter means of parts of said light having said second wavelength; and in a second instance, filtering the light by transmitting through the filter means parts of said light having said second wavelength and substantially preventing transmission through the filter means parts of said light having said first wavelength.

31. A method according to claim 30 including performing said filtering on light directed to the infra-red pixel sensor means.

32. A method according to claim 30 including performing said filtering on light for illuminating a tooth.

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33. A method according to any of claims 26 to 32 including generating said light remotely from said tooth, guiding the generating light to the proximity of the tooth, and illuminating the tooth with the guided light.

34. A method according to any of claims 26 to 33 including guiding said returned infra-red light to a location remote from the point of receipt of the returned light and generating image pixel values using said returned, guided light at said remote location.

35. A method according to any of claims 26 to 34 performed using an intra-oral probe.

36. A method according to any of claims 26 to 35 including polarizing according to a first polarization axis infra-red radiation generated for illuminating a tooth, and polarizing according to a second polarization axis transverse to the first polarization axis infra-red radiation returned from the illuminated tooth.

37. A method according to any of claims 26 to 36 including forming upon an infra-red pixel sensor means a real optical image using said infra-red light returned from an illuminated tooth.

38. A method according to any of claims 26 to 37 including producing one or more of said first and second images from said returned light.

39. A method according to claim 38 including co-registering a said first image and a said second image in respect of a common imaged subject, thereby to associate a given image pixel of the first image with a respective image pixel of the second image representing the same part of the imaged subject.

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40. A method according to any of claims 26 to 39 including generating image pixel values for a reference image of the illuminated tooth using reference infra-red light returned from the tooth and not first infra-red light nor second infra-red light, and providing such image pixel values for use.

41. A method according to claim 40 including, in respect of the given part of the imaged subject, calculating a first reflectance value R_1 associated with the part using one or more image pixel values of the first image, calculating a second reflectance value R_2 associated with the part using one or more image pixel values of the second image, calculating a reference reflectance value R_{ref} associated with the part using one or more image pixel values of the third image and determining from the first, second and reference reflectance values the values of the ratios R_1/R_{ref} and R_2/R_{ref} and providing the ratio values for use.

42. A method according to claim 41 including calculating a value $(R_2/R_{ref}-R_1/R_{ref})$ and providing the value for use.

43. A method according to any of claims 26 to 42 including generating light for illuminating the tooth and in a third instance, filtering the light by transmitting through a filter means parts of said light having said reference wavelength and substantially preventing transmission through the filter means of parts of said light having any of said first wavelength and said second wavelength.

44. A method according to any of claims 26 to 43 in which the first wavelength value is between 1300nm and 1550nm, and the second wavelength value is between 1550nm and 1800nm.

45. A method according to claim 44 in which the first wavelength value is between 1400nm and 1500nm, such as 1440nm, and the second wavelength value is between 1550nm and 1650nm, such as 1610nm.

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46. A method according to any of claims 26 to 45 including calculating a measure ($S_{carries}$) of the degree of caries present in the part using said measure of the degree of enamel lesion (S_e) and said measure of the degree of dentin lesion (S_d).

47. A computer programmed to implement the method of any of claims 26 to 46.

48. A computer program product comprising a computer-readable medium containing computer executable instructions which implement the method of any of claims 26 to 46 when executed on a computer.

49. A computer program containing computer executable instructions which implement the method of any of claims 26 to 46 when executed on a computer.

50. Apparatus according to any of claims 1 to 25 including computer means programmed for use in implementing the method of any of claims 26 to 46.

51. A computer program product comprising a computer-readable medium containing computer executable instructions for use in implementing the method of any of claims 26 to 46 when executed on apparatus according to claim 50.

52. A computer program containing computer executable instructions which implement the method of any of claims 26 to 46 when executed on apparatus according to claim 50.

53. A method substantially as described in any one embodiment hereinbefore with reference to, or substantially as illustrated in, any of the accompanying drawings.

54. Apparatus substantially as described in any one embodiment hereinbefore with reference to, or substantially as illustrated in, any of the accompanying drawings.

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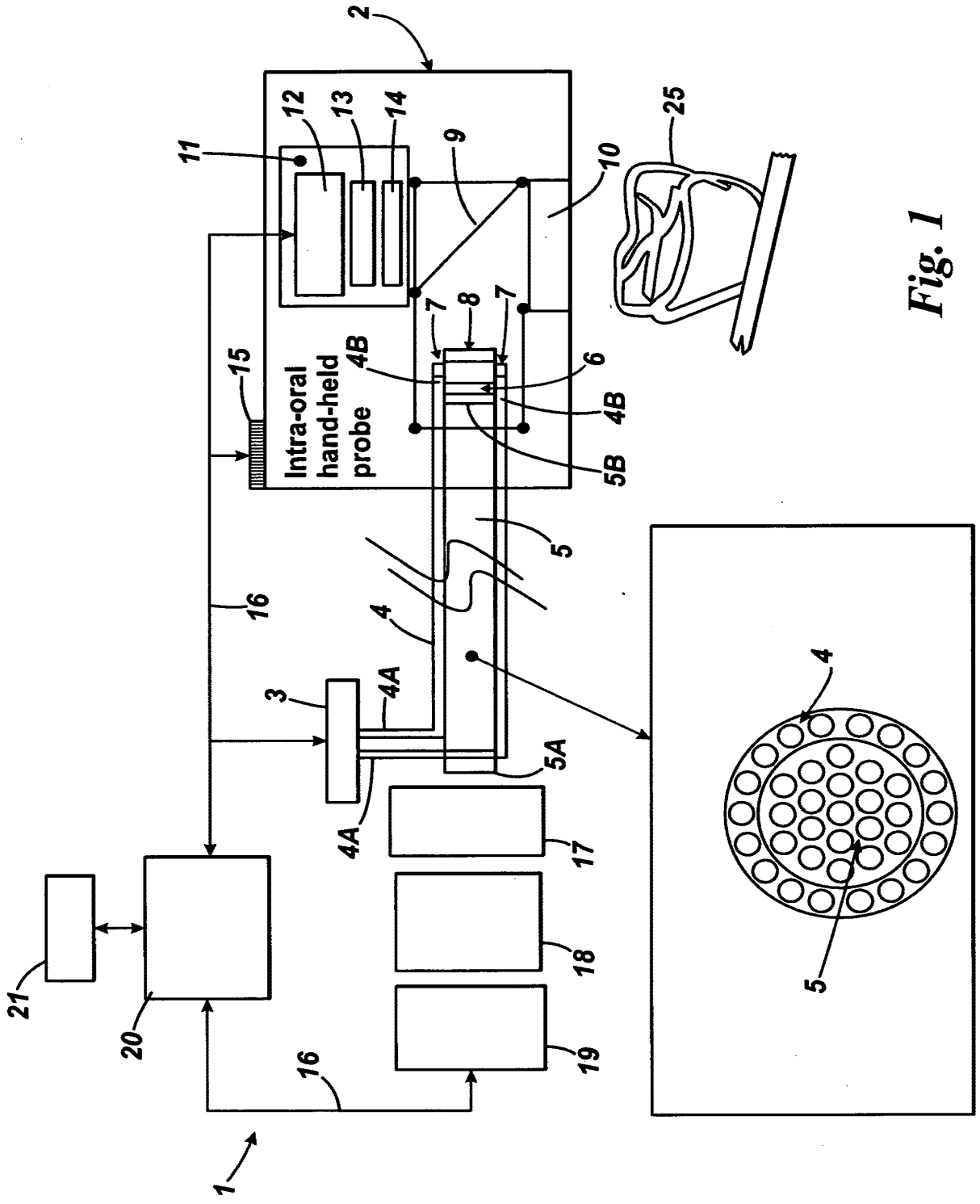

2
12
13
14
11
9
10
25
7
8
7
15
4B
6
Intra-oral
hand-held
probe
4B
5B
5
16
4
3
4A
5A
4A
17
18
19
21
20
16
1
4
5

Fig. 1

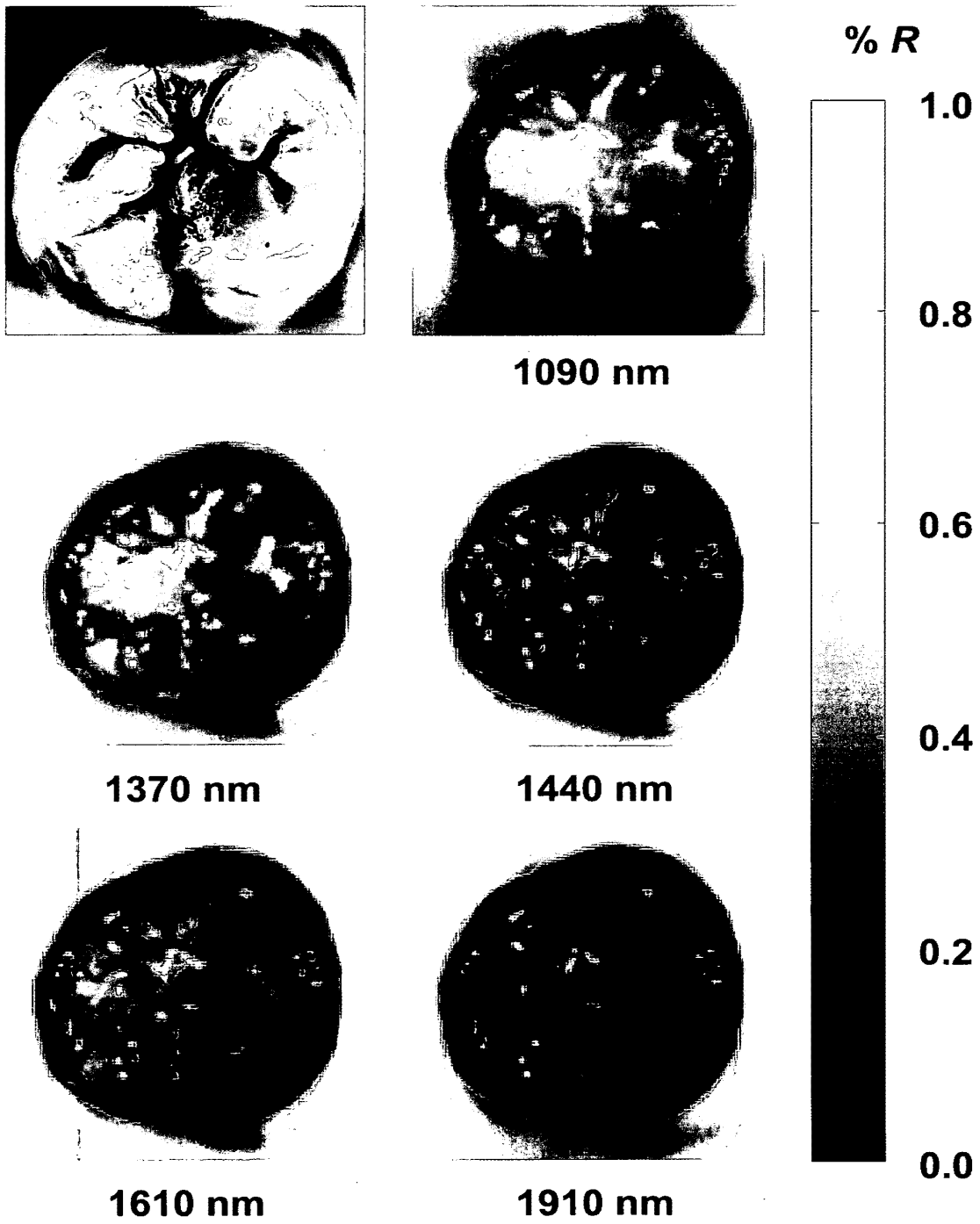
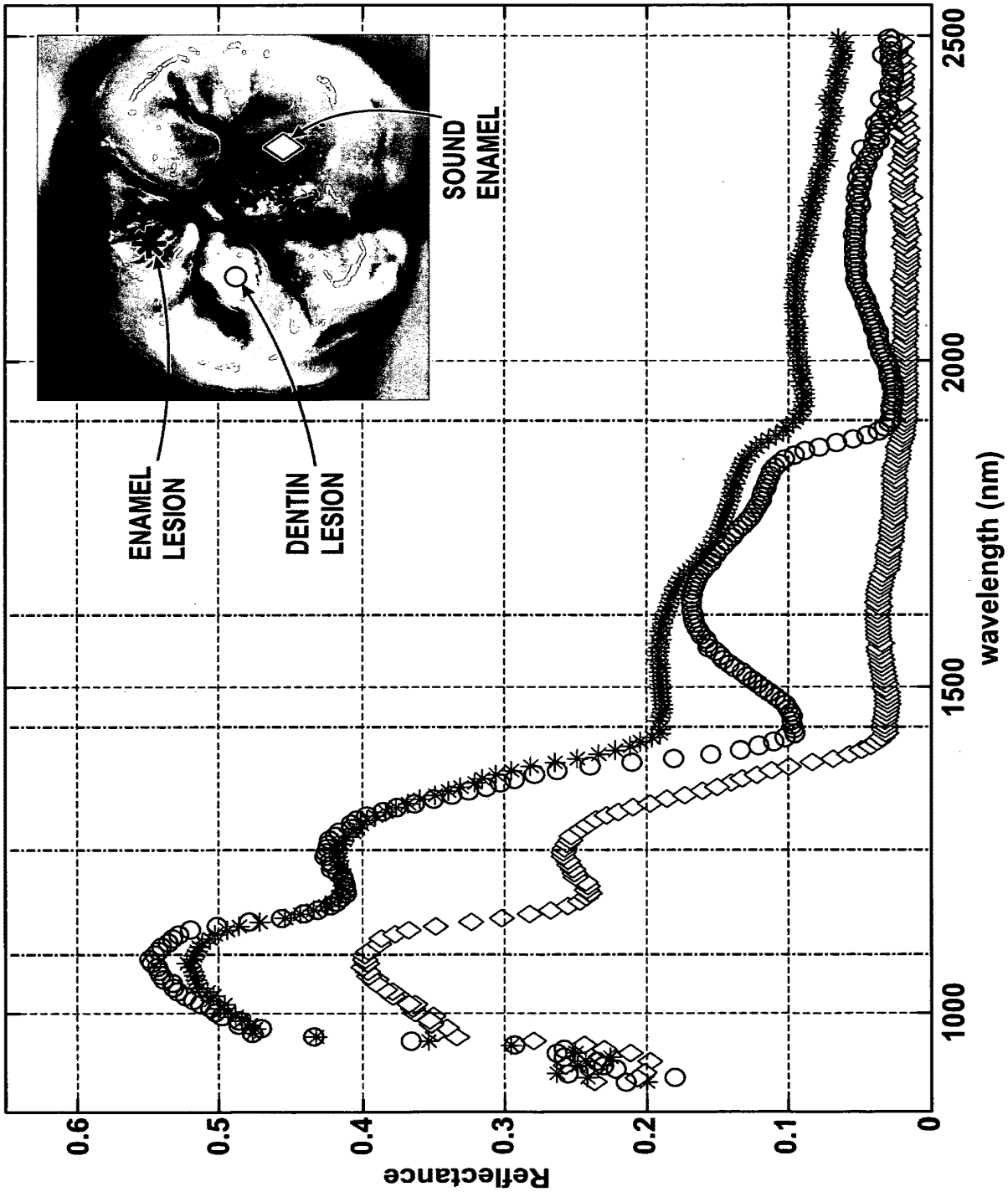


Fig. 2

Fig. 3


SOUND ENAMEL
ENAMEL LESION
DENTIN LESION
Reflectance
0.6
0.5
0.4
0.3
0.2
0.1
0
1000
1500
2000
2500
wavelength (nm)

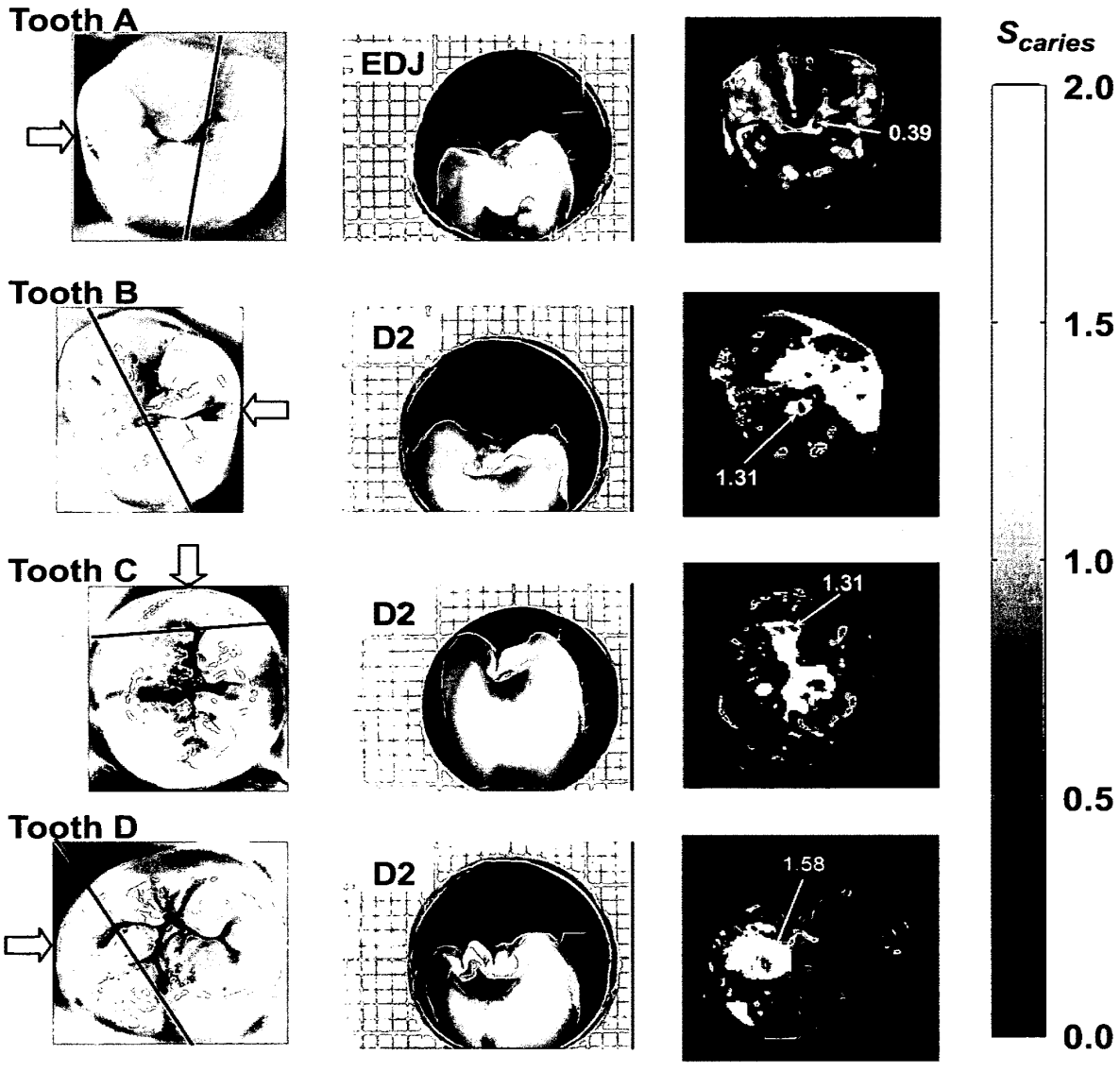

Tooth A
EDJ
0.39
Tooth B
D2
1.31
Tooth C
D2
1.31
Tooth D
D2
1.58
S_{caries}
2.0
1.5
1.0
0.5
0.0

Fig. 4

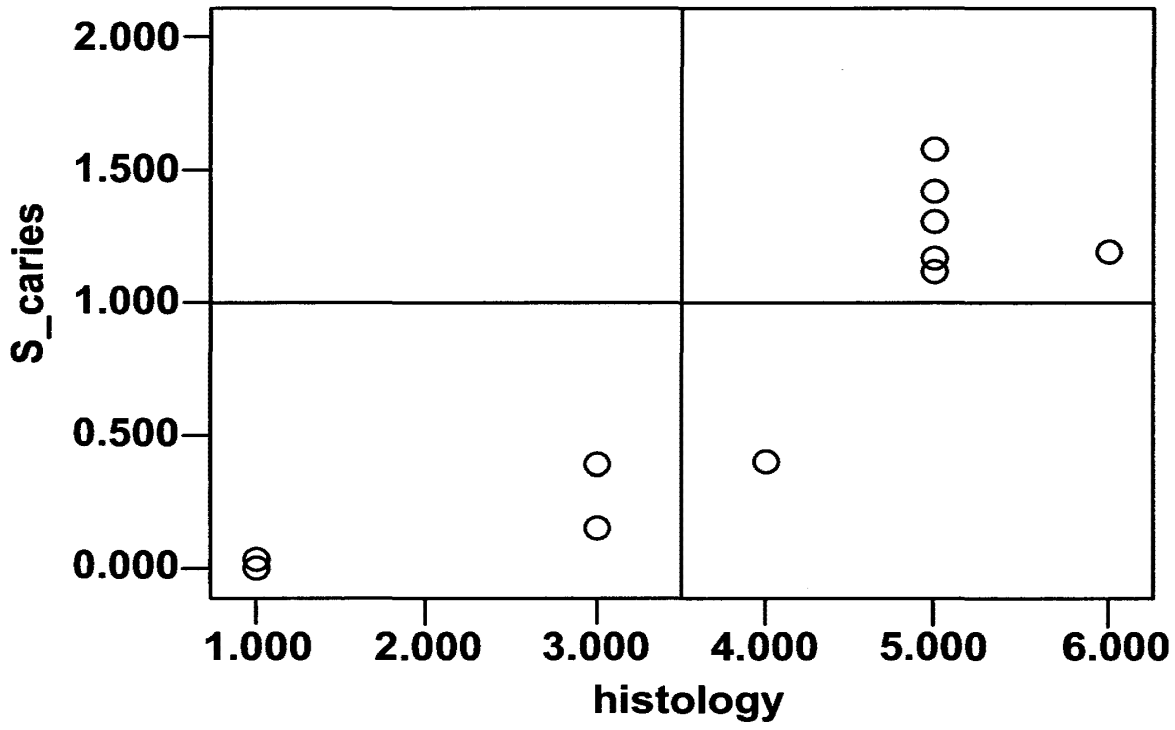

2.000
1.500
1.000
0.500
0.000
S_caries
1.000
2.000
3.000
4.000
5.000
6.000
histology

Fig. 5

Fig. 6



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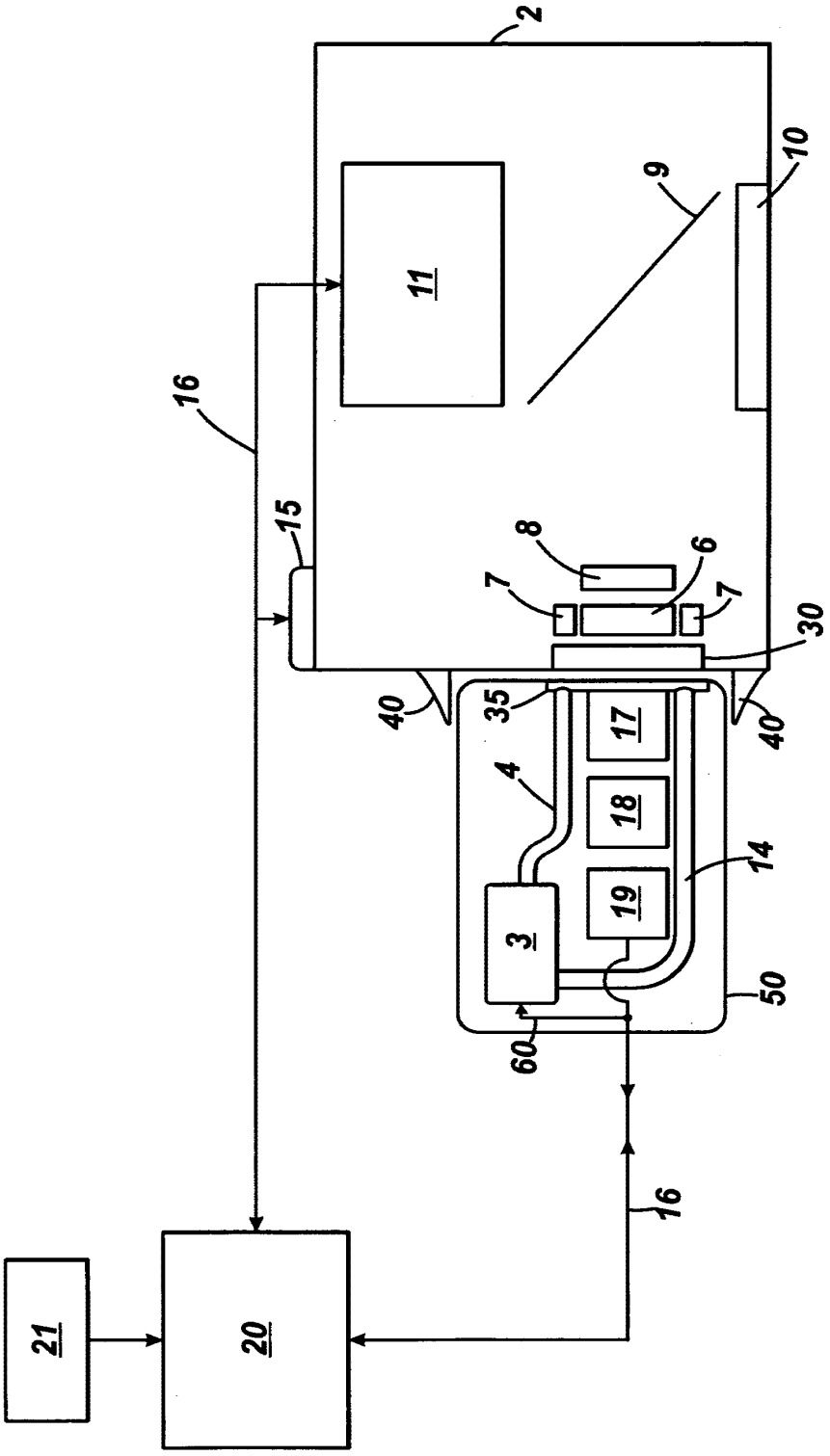


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001032

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00
ADD. A61B1/24

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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/134615 A1 (LOVELY PETER S [US]) 14 June 2007 (2007-06-14) paragraphs [0044], [0048], [0055], [0066], [0075], [0079] - [0086], [0090]; figures 8,10,11	1-52
Y	US 2005/181333 A1 (KARAZIVAN NAIM [CA] ET AL) 18 August 2005 (2005-08-18) paragraphs [0030] - [0036], [0038], [0043], [0046], [0068]	1-52
A	WO 98/52460 A (MEDICAL LASER TECHNOLOGIES LIM [GB]; COLLES MICHAEL JOHN [GB]) 26 November 1998 (1998-11-26) page 3, line 9 - page 4, line 14 page 6, lines 27-32 page 7, line 16 - page 10, line 11 page 10, line 35 - page 11, line 3	1,26

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2009	04/08/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kronberger, Raphael

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001032

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 2 042 085 A (DEGUDENT GMBH [DE]) 1 April 2009 (2009-04-01) paragraphs [0004], [0006], [0007], [0012] - [0016], [0027], [0041], [0051]	1,26
A	HSIAO-CHUAN WANG ET AL: "Selection of an appropriate laser wavelength for launching surface acoustic waves on tooth enamel" OPTICAL FIBRE TECHNOLOGY/AUSTRALIAN OPTICAL SOCIETY, 2006. ACOFT/AOS 2006. AUSTRALIAN CONFERENCE ON, IEEE, PISCATAWAY, NJ, USA, 10 July 2006 (2006-07-10), pages 99-101, XP031252053 ISBN: 978-0-9775657-1-9 Section IV. Conclusionfigures 2,3	24,25, 44,45
A	US 5 570 182 A (NATHEL HOWARD [US] ET AL) 29 October 1996 (1996-10-29) column 1, lines 47-64 column 4, lines 25-53 column 7, lines 44-64	1,26
A	US 2004/236232 A1 (JONUSAUSKAS GEDIMINAS [FR] ET AL) 25 November 2004 (2004-11-25) paragraphs [0002], [0014], [0015], [0017] - [0022], [0040] - [0043], [0051] - [0056]; figures 3,4	1,26

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 53,54

Claims 53,54 are not in compliance with the provisions of clarity of Article 6 PCT, as it is not possible for a skilled person to establish the exact subject-matter for which protection is sought. The non-compliance with the substantive provisions is to such an extent, that no search was performed for these claims.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2009/001032

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 53,54
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:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2009/001032

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007134615 A1	14-06-2007	NONE	
US 2005181333 A1	18-08-2005	AU 2003229419 A1	11-11-2003
		AU 2009200072 A1	05-02-2009
		WO 03094771 A2	20-11-2003
		CA 2385981 A1	08-11-2003
		CN 1703162 A	30-11-2005
		EP 1501407 A2	02-02-2005
		JP 2005524483 T	18-08-2005
		MX PA04011069 A	14-02-2005
		NZ 536730 A	27-04-2007
WO 9852460 A	26-11-1998	AU 7543398 A	11-12-1998
		EP 0984717 A1	15-03-2000
EP 2042085 A	01-04-2009	DE 102007046228 A1	09-04-2009
		US 2009087811 A1	02-04-2009
US 5570182 A	29-10-1996	NONE	
US 2004236232 A1	25-11-2004	CA 2448936 A1	05-12-2002
		EP 1392158 A1	03-03-2004
		FR 2825260 A1	06-12-2002
		WO 02096281 A1	05-12-2002
		JP 2004526550 T	02-09-2004

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

109543 7590 10/21/2016

Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

EXAMINER	
FEIN, ABRA S	

ART UNIT	PAPER NUMBER
2884	

NOTIFICATION DATE	DELIVERY MODE
10/21/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@brookskushman.com

Office Action Summary	Application No. 14/875,709	Applicant(s) ISLAM, MOHAMMED N.	
	Examiner Abra Fein	Art Unit 2884	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/21/2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *1-4* is/are allowed.

7)☒ Claim(s) *5-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *10/06/2015* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *6/22/2016, 7/21/2016*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

2. The terminal disclaimer filed on 07/06/2016 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 9,164,032 has been reviewed and is accepted. The terminal disclaimer has been recorded.

3. In view of the terminal disclaimer, the previous Double Patenting rejection is withdrawn.

Response to Amendment

4. The amendment filed 07/06/2016 has been accepted and entered. Accordingly, Claims 5-7, 9, 11-16, 18-20, and the Specification have been amended.

5. Clams 1-20 have been pending.

6. In view of the amendment, the previous rejection to the Specification has been withdrawn.

7. In view of the amendment, the previous rejection to claims 7 and 18 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Response to Arguments

8. In view of the amendment, the previous rejection to claims 5-20 under 35 U.S.C. 103(a) has been withdrawn, however upon further consideration in view of the amendment, a new ground(s) of rejection is made in view of Kleppe et al. (US 2011/0267688, hereinafter Kleppe; pub. Nov. 3, 2011), Fidler et al. (US 2013/0327966; pub. Dec. 12, 2013), and Doppke et al. (US 2005/0133691, hereinafter Doppke; pub. Jun. 23, 2005.

Claim Rejections - 35 USC § 103

9. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 5, 8, 10, 12, 14, 17, and 20** are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Polli et al. (US 2006/0283931, hereinafter Polli) in view of Banet, Rubio Guivernau et al. (US 2014/0078510, hereinafter Rubio Guivernau; PCT filed May 18, 2012), and Kleppe et al. (US 2011/0267688, hereinafter Kleppe; pub. Nov. 3, 2011).

13. Regarding **Claim 5**, Polli teaches a measurement system comprising: a light source comprising: a plurality of semiconductor sources configured to generate an output optical beam; an apparatus configured to receive a received portion of the output optical beam and to deliver an analysis output beam to a sample; a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers [0076; 0013, Polli inherently teaches

wavelengths between 700 nanometers and 2500 nanometers since that is the definition of near-infrared]. Polli does not explicitly a personal device and a remote device.

Banet teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link; a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal to process the received output status to generate processed data and to store the processed data [0005], further comprising a light source comprising a plurality of semiconductor source that are light emitting diodes [0043]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with a personal device and remote device, as taught by Banet, for the benefit of transmitting and displaying information generated.

Rubio Guivernau teaches an apparatus comprising a plurality of lenses configured to receive a portion of the output beam (CLM 9). Rubio Guivemau further teaches the benefit of optical power efficiency [0049]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with the plurality of lenses configured to receive a portion of the output beam, as taught by Rubio Guivemau, for the benefit of optical power efficiency.

Kleppe teaches a correlation between a signal-to-noise ratio and pulse rate/light intensity [0115]. Kleppe further teaches the benefit of obtaining an optimum detection signal [0115]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with correlation a signal-to-noise ratio with a pulse rate and light intensity, as taught by Kleppe, for the bneefit of obtaining an optimum detection signal.

14. Regarding **Claim 14**, Polli teaches a measurement system comprising: a light source comprising a plurality of semiconductor sources configured to generate an output optical beam; a measurement apparatus configured to receive a received portion of the output optical beam with one or more optical

wavelengths, and to deliver an analysis output beam to a sample; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal [0076; 0013, Polli inherently teaches wavelengths between 700 nanometers and 2500 nanometers since that is the definition of near-infrared].

Banet teaches wearable measurement device further comprising a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link; a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data [0005], further comprising a light source comprising a plurality of semiconductor source that are light emitting diodes [0043]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with a personal device and remote device, as taught by Banet, for the benefit of transmitting and displaying information generated.

Rubio Guivernau teaches an apparatus comprising a plurality of lenses configured to receive a portion of the output beam (CLM 9). Rubio Guivemau further teaches the benefit of optical power efficiency [0049]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with the plurality of lenses configured to receive a portion of the output beam, as taught by Rubio Guivemau, for the benefit of optical power efficiency.

Kleppe teaches a correlation between a signal-to-noise ratio and pulse rate/light intensity [0115]. Kleppe further teaches the benefit of obtaining an optimum detection signal [0115]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with correlation a signal-to-noise ratio with a pulse rate and light intensity, as taught by Kleppe, for the bneefit of obtaining an optimum detection signal.

15. Regarding **Claims 8 and 17**, Polli as adapted above teaches the systems of claims 5 and 14, but does not teach specifics of the remote device. Banet teaches the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server, and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data [0152]. Banet further teaches the benefit of providing medical diagnostic information to medical professionals [0152]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as taught by Polli as adapted above, with having the remote device configured to transmit at least a portion of the processed data to other location, as taught by Banet, for the benefit of providing medical diagnostic information to medical professionals.

16. Regarding **Claim 10**, Polli as adapted above teaches the systems of claims 5 and 14. Polli does not teach the output signal comprises physiological parameters. Banet teaches the output signal comprises one or more physiological parameters, and the remove device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time [0063; 0080]. Banet further teaches the benefit of showing changes in values of the physiological parameters over periods of time [0080]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as taught by Polli as adapted above, with the output signal comprising one or more physiological parameters, wherein the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time, as taught by Banet, for the benefit of showing changes in values of the physiological parameters over periods of time.

17. Regarding **Claims 12 and 20**, Polli as adapted above teaches the measurement system of claims 5 and 14. Polli does not teach the receiver further comprises one or more filters in front of one or more detectors. Kleppe teaches the use of a filter F in front of a detector [0040]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to have the receiver further comprise a

filter, since it has been held to be within the general skill of a working in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

18. **Claims 6-7, 9, 15-16, and 18** are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Polli and Banet, Rubio Guivernau, and Kleppe as applied to claims 5 and 14 above, and further in view of Fidler et al. (US 2013/0327966, hereinafter Fidler et al.; pub. Dec. 12, 2013).

19. Regarding **Claims 6 and 15**, Polli as adapted above teaches the system of claims 5 and 14. Polli does not teach the receiver is configured to be synchronized to the light source. Fidler teaches the receiver is configured to be synchronized to the light source (Fig. 5). The combination of the measurement system, as taught by Polli, with the receiver being configured to be synchronized to the light source, as taught by Fidler, would have been obvious to a person of ordinary skill in the art at the time of the invention to try, as a person with ordinary skill has good reason to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success, since there are a limited number of ways in which the receiver and light source can be configured together.

20. Regarding **Claims 7 and 16**, Polli as adapted above teaches the system of Claims 5 and 14. Polli does not teach at least one of the light emitting diodes emits light with a bandwidth between 20 nanometers to 40 nanometers. Fidler teaches that conventional LEDs have a bandwidth of approximately 30nm, falling between 20nm to 40nm [0080]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the system, as taught by Polli, with the light emitting diodes having a bandwidth between 20nm and 40nm, as taught by Fidler, for the benefit of using what is conventionally known in the art.

21. Regarding **Claims 9 and 18**, Polli as adapted above teaches the system of claims 5 and 14. Polli does not teach the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode. Fidler teaches a receiver is located a first distance from a first one of the

plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode (Fig. 5; [0012; 0064]). The combination of the measurement system, as taught by Polli, with the receiver being a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting dioses, as taught by Fidler, would have been obvious to a person of ordinary skill in the art at the time of the invention to try, as a person with ordinary skill has good reason to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success, since there are a limited number of ways in which the receivers and light emitting diodes can be arranged.

22. **Claims 11, 13, and 19** is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Polli and Banet, Rubio Guivernau, Kleppe, and Fidler as applied to claims 9 and 18 above, and further in view of Doppke et al. (US 2005/0133691, hereinafter Doppke; pub. Jun. 23, 2005).

23. Regarding **Claims 11 and 19**, Polli as adapted above teaches the measurement system of claims 9 and 18. Polli does not teach the output signal is generated in part by comparing the first and second signals. Doppke teaches output signals generated in response to a comparison of signals received on the first and second input terminals (CLM 18). Doppke further teaches the benefit of determining the presence of signal detection (CLM 2). It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system of Polli as adapted above, with the output signal being generated in part by comparing the first and second signals, as taught by Doppke, for the benefit of determining the presence of signal detection.

24. Regarding **Claim 13**, Polli as adapted above teaches the measurement system of claim 5. Polli does not teach the output optical beam comprises a plurality of optical wavelengths, and the output signal is generated in part by comparing signals at different optical wavelengths. Fidler teaches the output optical beam comprises a plurality of optical wavelengths (Fig. 5). The combination of the measurement system, as taught by Polli as adapted above, with the beam comprising a plurality of optical wavelengths, as taught by Fidler, would have been obvious to a person of ordinary skill in the art at the time of the

invention to try, as a person with ordinary skill has good reason to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success, since there are a limited number of ways in which the optical wavelengths can either be the same or different. Doppke teaches output signals generated in response to a comparison of signals received on the first and second input terminals (CLM 18). Doppke further teaches the benefit of determining the presence of signal detection (CLM 2). It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system of Polli as adapted above, with the output signal being generated in part by comparing the first and second signals, as taught by Doppke, for the benefit of determining the presence of signal detection.

Allowable Subject Matter

25. **Claims 1-4** are allowed.

26. The following is an examiner's statement of reasons for allowance:

27. Regarding **Claim 1**, Polli et al. (US 2006/0283931, hereinafter Polli) teaches a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductor sources configured to generate an input beam; a measurement apparatus configured to receive a received portion of the output optical beam, which is a delivered portion of the output optical beam; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal wherein at least a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 700 nm and approximately 2500 nm [0076; 0013].

Islam (US 2009/0028193, hereinafter Islam) teaches the use of optical amplifiers configured to receive at least a portion of an input beam and to output an intermediate beam from at least one of the one or more optical amplifiers (Abstract).

Buchter et al. (US 8,000,574, hereinafter Buchter) teaches one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least the portion of the intermediate beam to form a first optical beam (col. 8, lines 18-20).

Islam (US 2006/0268393, hereinafter Islam 2) teaches a nonlinear element configured to receive at least a portion of an optical beam and to broaden a spectrum associated with at least a portion of that optical beam through a nonlinear effect in the nonlinear element to form an output optical beam with an output beam broadened spectrum [0039]. Buchter further teacher a supercontinuum radiation source that has a high degree of spatial coherence compared to thermal light sources (col. 1, lines 13-17).

Banet et al. (US 2010/0160798, hereinafter Banet; pub. Jun. 24, 2010) teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link [0005].

Islam (US 2012/0239013, hereinafter Islam 3) teaches a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductor sources configured to generate an input beam; one or more optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the one or more optical amplifiers; and one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to form a first optical beam; a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum (Abstract); and wherein at least a portion of the one or more fibers is a fused silica fiber [0004], a measurement apparatus configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample (Fig. 20); and a receiver [0138].

Liu (US 2014/0249427, hereinafter Liu; PCT filed Dec. 15, 2011) teaches a fused silica fiber with a core diameter less than approximately 400 microns [0027].

Although each aspect of the claim is taught individually by multiple references, there is insufficient motivation to render the claim obvious and to combine all seven references. The prior art of record does not disclose or reasonably suggest, along with the other claim limitations, a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more

semiconductors sources, one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers, one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam, and a nonlinear element configured to receive at least a portion of a first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 700 nm and approximately 2500 nm; a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam; a receiver; and a personal device.

28. **Claims 2-4** are allowable due to dependency.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abra Fein whose telephone number is (571)272-0552. The examiner can normally be reached on Monday-Friday 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID PORTA/
Supervisory Patent Examiner, Art Unit 2884

/A. F./
Examiner, Art Unit 2884

Notice of References Cited	Application/Control No. 14/875,709	Applicant(s)/Patent Under Reexamination ISLAM, MOHAMMED N.	
	Examiner Abra Fein	Art Unit 2884	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-2011/0267688 A1	11-2011	Kleppe; Ingo	G02B21/0036	359/385
*	C	US-2013/0327966 A1	12-2013	Fidler; Franz	G02B26/04	250/578.1
*	D	US-2005/0133691 A1	06-2005	Doppke, Harald	H04B10/6933	250/214A
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	F	US-				
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7771320	B2	2010-08-10	Riley, et al.	
	2	6619835	B2	2003-09-16	Kita	
	3	9326712	B1	2016-05-03	Kiani	
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	7	8472108		2013-06-25	Islam	

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Receipt date: 06/22/2016	Application Number	14875709 14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
(Not for submission under 37 CFR 1.99)	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Ex. Wolz. Fr.

Receipt date: 06/22/2016	Application Number	14875709 14875709 - GAU: 2884
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	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

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EXAMINER SIGNATURE

Examiner Signature	/Abra Fein/	Date Considered	10/11/2016

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Receipt date: 06/22/2016	Application Number	14875709 14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
(Not for submission under 37 CFR 1.99)	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2016-06-22
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Exhibit 2002

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	**Art Unit**
	ABRA FEIN	2884

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/13/2016	10/11/2016							
	1	✓	=							
	2	✓	=							
	3	✓	=							
	4	✓	=							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	✓	✓							
	18	✓	✓							
	19	✓	✓							
	20	✓	✓							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	(14/108986).APP.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:07
S2	1029	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:07
S3	269	((Mohammed) near2 (Islam)).INV.	US-PGPUB; USPAT	OR	ON	2015/06/15 12:07
S4	7	(("6885683") or ("6281471") or ("6340806") or ("6301271") or ("7294105") or ("20100046067") or ("20080105665")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:08
S5	52	(("5084880") or ("5180378") or ("5400165") or ("5458122") or ("5617871") or ("5631758") or ("5687734") or ("5696778") or ("5704351") or ("5718234") or ("5748103") or ("5855550") or ("5862803") or ("5847305") or ("5912749") or ("5944659") or ("5957854") or ("6014249") or ("6043927") or ("6289238") or ("6333803") or ("6364834") or ("6381391") or ("6402691") or ("6407853") or ("6441747") or ("6443890") or ("6454705") or ("6480656") or ("6549702") or ("6603910") or ("6659947") or ("6802811") or ("7167300") or ("7209657") or ("7263288") or ("7519253") or ("20020013518") or ("20020019584") or ("20020032468") or ("20020082612") or ("20020109621") or ("20020115914") or ("20020178003") or ("20040174914") or ("20040240037") or ("20050111511") or ("20060245461") or ("20060268393") or ("20070078348") or ("20090028193") or ("20090204110")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:12
S6	4	(("7787503") or ("7800818") or ("8000574") or ("6611643")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:13
S7	82	(("4063106") or ("4158750") or ("4221997") or ("4275266") or ("4374618") or ("4403605") or ("4462080") or ("4516207") or ("4523884") or ("4605080") or ("4641292") or ("4704696") or ("4728974") or ("4762455") or ("4776016") or ("4958910") or	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:19

		("4989253") or ("5078140") or ("5084880") or ("5086401") or ("5134620") or ("5142930") or ("5180378") or ("5191628") or ("5218655") or ("5230023") or ("5267256") or ("5267323") or ("5300097") or ("5303148") or ("5305427") or ("5313306") or ("5323404") or ("5345538") or ("5408409") or ("5544654") or ("5572999") or ("5695493") or ("5696778") or ("5792204") or ("5812978") or ("5950629") or ("5970457") or ("6014249") or ("6185535") or ("6200309") or ("6224542") or ("6246707") or ("6273858") or ("6278975") or ("6301273") or ("6337462") or ("6340806") or ("6350261") or ("6374006") or ("6407853") or ("6436107") or ("6442430") or ("6450172") or ("6453201") or ("6458120") or ("6462500") or ("6463361") or ("6567431") or ("6605080") or ("6625180") or ("6631025") or ("6659999") or ("6760148") or ("6885498") or ("6885683") or ("6943936") or ("7027467") or ("7060061") or ("7167300") or ("7259906") or ("7433116") or ("20020032468") or ("20020082612") or ("20020128846") or ("20020178003") or ("20040174914")).PN.				
S8	3	(("6246896") or ("6285897") or ("6847336")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:21
S9	30	(("5747806") or ("5115673") or ("6512936") or ("6534012") or ("6640117") or ("6788965") or ("6816241") or ("6738652") or ("6587702") or ("6864978") or ("6990364") or ("7010336") or ("7133710") or ("7233816") or ("7299080") or ("7317938") or ("7395158") or ("7519406") or ("7620674") or ("7697966") or ("7787924") or ("8145286") or ("6773922") or ("7807718") or ("20100331637") or ("20110143364") or ("20030022126") or ("20060223032") or ("20100322490") or ("20120013722")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:54
S10	2	(("8472108") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:54
S11	168	S4 S5 S6 S7 S8 S9 S10	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/15 13:07
S12	2	((12/206432) or (10/652276) or	US-	OR	OFF	2015/06/15

		(10/757341)).APP.	PGPUB; USPAT			14:48
S13	5	(("WOadj2014105520") or ("WOadj2014143276A9") or ("WOadj2014143276") or ("WOadj2013148656") or ("EPadj2831566") or ("WOadj2013148666") or ("EPadj2831565") or ("20130265568") or ("WOadj2014105521") or ("8859969") or ("20130256534") or ("20140236021") or ("CAadj2648549") or ("WOadj2007117867") or ("20060283931") or ("EPadj2011047") or ("EPadj1671094") or ("WOadj2005031302")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 14:51
S14	16	WO adj "2014105520" WO adj 2014143276A9 WO adj "2014143276" WO adj "2013148656" EP adj "2831566" WO adj "2013148666" EP adj "2831565" "20130265568" WO adj "2014105521" "8859969" "20130256534" "20140236021" CA adj "2648549" WO adj "2007117867" "20060283931" EP adj "2011047" EP adj "1671094" WO adj "2005031302"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/15 14:51
S15	7	(("6885683") or ("6281471") or ("6340806") or ("6301271") or ("7294105") or ("20100046067") or ("20080105665")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S16	52	(("5084880") or ("5180378") or ("5400165") or ("5458122") or ("5617871") or ("5631758") or ("5687734") or ("5696778") or ("5704351") or ("5718234") or ("5748103") or ("5855550") or ("5862803") or ("5847305") or ("5912749") or ("5944659") or ("5957854") or ("6014249") or ("6043927") or ("6289238") or ("6333803") or ("6364834") or ("6381391") or ("6402691") or ("6407853") or ("6441747") or ("6443890") or ("6454705") or ("6480656") or ("6549702") or ("6603910") or ("6659947") or ("6802811") or ("7167300") or ("7209657") or ("7263288") or ("7519253") or ("20020013518") or ("20020019584") or ("20020032468") or ("20020082612") or ("20020109621") or ("20020115914") or ("20020178003") or ("20040174914") or ("20040240037") or ("20050111511") or ("20060245461") or ("20060268393") or ("20070078348") or ("20090028193") or ("20090204110")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S17	4	(("7787503") or ("7800818") or ("8000574") or ("6611643")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S18	82	(("4063106") or ("4158750") or ("4221997") or ("4275266") or ("4374618") or ("4403605") or	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37

		("4462080") or ("4516207") or ("4523884") or ("4605080") or ("4641292") or ("4704696") or ("4728974") or ("4762455") or ("4776016") or ("4958910") or ("4989253") or ("5078140") or ("5084880") or ("5086401") or ("5134620") or ("5142930") or ("5180378") or ("5191628") or ("5218655") or ("5230023") or ("5267256") or ("5267323") or ("5300097") or ("5303148") or ("5305427") or ("5313306") or ("5323404") or ("5345538") or ("5408409") or ("5544654") or ("5572999") or ("5695493") or ("5696778") or ("5792204") or ("5812978") or ("5950629") or ("5970457") or ("6014249") or ("6185535") or ("6200309") or ("6224542") or ("6246707") or ("6273858") or ("6278975") or ("6301273") or ("6337462") or ("6340806") or ("6350261") or ("6374006") or ("6407853") or ("6436107") or ("6442430") or ("6450172") or ("6453201") or ("6458120") or ("6462500") or ("6463361") or ("6567431") or ("6605080") or ("6625180") or ("6631025") or ("6659999") or ("6760148") or ("6885498") or ("6885683") or ("6943936") or ("7027467") or ("7060061") or ("7167300") or ("7259906") or ("7433116") or ("20020032468") or ("20020082612") or ("20020128846") or ("20020178003") or ("20040174914")).PN.				
S19	3	(("6246896") or ("6285897") or ("6847336")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S20	30	(("5747806") or ("5115673") or ("6512936") or ("6534012") or ("6640117") or ("6788965") or ("6816241") or ("6738652") or ("6587702") or ("6864978") or ("6990364") or ("7010336") or ("7133710") or ("7233816") or ("7299080") or ("7317938") or ("7395158") or ("7519406") or ("7620674") or ("7697966") or ("7787924") or ("8145286") or ("6773922") or ("7807718") or ("20100331637") or ("20110143364") or ("20030022126") or ("20060223032") or ("20100322490") or ("20120013722")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S21	2	(("8472108") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S22	168	S15 S16 S17 S18 S19 S20 S21	US-PGPUB;	OR	ON	2015/06/16 09:37

			USPAT; EPO; JPO; DERWENT			
S23	2	((12/206432) or (10/652276) or (10/757341)).APP.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S24	5	(("WOadj2014105520") or ("WOadj2014143276A9") or ("WOadj2014143276") or ("WOadj2013148656") or ("EPadj2831566") or ("WOadj2013148666") or ("EPadj2831565") or ("20130265568") or ("WOadj2014105521") or ("8859969") or ("20130256534") or ("20140236021") or ("CAadj2648549") or ("WOadj2007117867") or ("20060283931") or ("EPadj2011047") or ("EPadj1671094") or ("WOadj2005031302")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S25	16	WO adj "2014105520" WO adj 2014143276A9 WO adj "2014143276" WO adj "2013148656" EP adj "2831566" WO adj "2013148666" EP adj "2831565" "20130265568" WO adj "2014105521" "8859969" "20130256534" "20140236021" CA adj "2648549" WO adj "2007117867" "20060283931" EP adj "2011047" EP adj "1671094" WO adj "2005031302"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:37
S26	185	S22 S23 S24 S25	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:37
S27	126	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:44
S28	1	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same semiconductor same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:46
S29	24	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconductor and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:47
S30	24	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconduct$5 and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:47

S31	21	S26 and ((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconduct$5 and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:48
S32	648	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same semiconduct$5 same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:05
S33	123	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:08
S34	5	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:37
S35	6	S25 and (semiconduct$5 multiplex$5)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:50
S36	2	S25 and (multiplex$5)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:50
S37	6	S25 and (semiconduct$5 multiplex$5 mux)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:51
S38	8	S25 and (laser (super near luminesc$5 near diode)LED (light near emit$5 near diode))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:53
S39	9	S25 and (fiber)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:54
S40	1	S25 and (FTIR)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:56
S41	4	S25 and (fourier)	US-PGPUB; USPAT;	OR	ON	2015/06/16 10:59

			EPO; JPO; DERWENT			
S42	4	S25 and (fourier with (IR infrared infra-red))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:59
S43	4	S25 and (fourier near4 (IR infrared infra-red))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:59
S44	575	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:21
S45	8428	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:21
S46	3	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:22
S47	59	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:07
S48	4	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:08
S49	23	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S50	2	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S51	23	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S52	7	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)same fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12

S53	115	S26 and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S54	43	S26 and(fiber with beam)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S55	2	S26 and(fiber with beam)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S56	9	S26 and(FTIR FT-IR ("fourier transform infrared"))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:20
S57	270	((Mohammed) near2 (Islam)).INV.	US-PGPUB; USPAT	OR	ON	2015/06/16 13:22
S58	67	S57 and multiplexer.clm.	US-PGPUB; USPAT	OR	ON	2015/06/16 13:22
S59	21	S57 and ((multiplexer and semiconductor and fibers).clm.)	US-PGPUB; USPAT	OR	ON	2015/06/16 13:23
S60	2	S57 and ((multiplexer and semiconductor and fibers and FTIR).clm.)	US-PGPUB; USPAT	OR	ON	2015/06/16 13:23
S61	125	S57 and (broaden$5)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S62	64	S57 and (broaden$5 with (nonlinear non-linear))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S63	29	S57 and (broaden$5 with (nonlinear non-linear) with spectrum)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S64	9	S57 and (broaden$5 near4(nonlinear non-linear) with spectrum)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S65	2	S57 and (organic with (overtone (combination$5 absor%8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:31
S66	2	S57 and (organic with (overtone (combination$5 near absor$8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:32
S67	206	(organic with (overtone (combination$5 near absor$8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:32
S68	62	(organic with (overtone))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:40
S69	14	(organic with (overtone))and "250".clas.	US-PGPUB;	OR	ON	2015/06/16 16:40

			USPAT			
S70	1	("6105823").PN.	US-PGPUB; USPAT	OR	OFF	2015/06/17 16:05
S71	320	abrahamsson.in.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/17 16:05
S72	4	abrahamsson.in. and multiplexer	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/17 16:06
S73	1034	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2015/07/23 13:49
S74	5	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:49
S75	2	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S76	125	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S77	8	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)same fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S78	14	(organic with (overtone))and "250".clas.	US-PGPUB; USPAT	OR	ON	2015/07/23 13:50
S79	1	(sample) with (overtone or "combinational absorption band") with(wavelength near range) .clm.	US-PGPUB; USPAT	OR	ON	2015/07/23 13:53
S81	7	250/338.4 and @pd>"20150625"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/24 11:51
S89	1	("20100161794").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/13 11:39
S90	606	banet.in.	US-PGPUB; USPAT; EPO; JPO;	OR	ON	2016/05/13 11:40

			DERWENT			
S91	5	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/05/13 11:58
S92	0	S91 and (LED light near emit$7 near diode) with puls$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:58
S93	93	(near-infrared near-IR)with(LED light near emit$7 near diode) with puls$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:59
S94	8	(near-infrared near-IR)with(LED light near emit$7 near diode) with puls$5 and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:59
S95	1059	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/05/13 13:56
S96	1	("9164032").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/17 14:53
S97	1	("0612310").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/17 15:31
S98	1	("20140249427").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/17 15:32
S99	1067	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/10/11 11:38
S100	0	(light near source) with increas$4 near2 signal$to$noise near ratio with light near intensit$4 with semiconduct$4 with pulse near2 rate	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:39
S101	0	(light near source) with increas$4 near2 signal$to$noise near ratio with light near intensit$4 with semiconduct$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:40
S102	0	(light near source) with increas$4 near2 "signal to noise" near ratio with light near intensit$4 with semiconduct$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:40
S103	0	(light near source) with increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:57
S104	0	(light) with increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58

S105	0	(source) with increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58
S106	0	increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58
S107	136	increas$4 near2 "signal to noise" near ratio	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58
S108	0	increas$4 near2 "signal to noise" near ratio with (increas$4 near2 light near intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:59
S109	0	increas$4 near2 "signal to noise" near ratio with (light near intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:59
S110	1	increas$4 near2 "signal to noise" near ratio with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:59
S111	31	"signal to noise" near ratio with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:04
S112	1	increas$4 near4 "signal to noise" near ratio with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:05
S113	1	(increas$4 near4 "signal to noise ratio") with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:06
S114	0	(increas$4 near4 "signal to noise ratio") with (pulse near rate)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:06
S115	10	(increas$4 near4 (signal near2 noise near ratio)) with (pulse near rate)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:06
S116	2	(increas$4 near4 (signal near2 noise near ratio)) with increas$4 near2(pulse near rate)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:07

S117	7	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$ or US-20090244288-$ or US-20140249427-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/10/11 13:22
S118	5	S117 and (lens lenses)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:22
S119	1	S117 and ((lens lenses)with sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:23
S120	1	S117 and ((lenses)with sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:24
S121	0	S117 and ((plurality near2 lenses)with sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:25
S122	3	((plurality near2 lenses)with (output near2 beam) near4 sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:25
S123	491	(G01N33/15.cpc. G01N21/359.cpc. G01N33/49.cpc.)and @pd>"20160513"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 14:02
S132	1	("8180422").PN.	US-PGPUB; USPAT	OR	OFF	2016/10/11 14:45
S133	19	(("8180422") or ("7771320") or ("6619835") or ("9326712") or ("5267152") or ("7356364") or ("5246004") or ("8472108") or ("20100217102") or ("20120310062") or ("20120316455") or ("20140275854") or ("20140275852") or ("20160045118") or ("20110208015") or ("20110040197") or ("20070021670") or ("20110282167") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2016/10/11 14:48
S134	0	S133 and signal adj to adj noise near2 ratio	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 14:49

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S80	0	(sample) with (overtone or "combinational absorption band") with(wavelength near	USPAT	OR	ON	2015/07/23 13:53

		range) .clm.				
S82	7	250/338.4 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:51
S83	47202	G01N$21/35 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:51
S84	54478	A61B$5/1455 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:51
S86	54480	A61B$5/0075 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:52
S87	9513	H01S$3/302 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:52
S88	0	(S82 S83 S84 S86 S87)and (non-destructive with non-contact with measur$5) with deliver$5.clm.	USPAT	OR	ON	2015/07/24 11:54
S128	71	(G01N33/15.cpc. G01N21/359.cpc. G01N33/49.cpc.)and @pd>"20160513"	USPAT	OR	ON	2016/10/11 14:02
S130	45	250/338.4 and @pd>"20160513"	USPAT	OR	ON	2016/10/11 14:02
S131	0	(increas$4 near4 (signal near2 noise near ratio)) with increas$4 near2(pulse near rate).clm.	USPAT	OR	ON	2016/10/11 14:35

10/11/2016 2:51:49 PM
C:\Users\afein\Documents\EAST\Workspaces\14\14875709.wsp

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8180422	B2	2012-05-15	Rebec	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	102010012987	DE	A1	2010-10-07	FRAUNHOFER GES FORSCHUNG		
	2	2005013843	WO	A2	2005-02-17	The Regents of the University of California		
	3	2007061772	WO	A2	2007-05-31	OMNI SCIENCES, INC.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Exs Web2.1rc

Receipt date: 07/21/2016	Application Number	14875709 14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2015-10-06
(Not for submission under 37 CFR 1.99)	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

	4	2009130464	WO	A1	2009-10-29	UNIVERSITY OF MANCHESTER		

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	VINAY V. ALEXANDER ET AL.; Modulation Instability High Power All-Fiber Supercontinuum Lasers And Their Applications; Optical Fiber Technology 18; 2012; pages 349-374.	
	2	ROBERT S. JONES ET AL.; Near-Infrared Transillumination At 1310-nm For The Imaging Of Early Dental Decay; Volume 11, No. 18; Optics Express 2259; September 8, 2003	
	3	Extended European Search Report for European Application No. 13867874.3 dated July 15, 2016	
	4	Extended European Search Report for European Application No. 13867892.5 dated July 22, 2016	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Abra Fein/	Date Considered	10/11/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Ets v4.2.1 rc

Receipt date: 07/21/2016	Application Number	14875709 14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2016-07-21
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	Art Unit
	ABRA FEIN	2884

CPC- SEARCHED		
Symbol	Date	Examiner
G01N33/15, G01N21/359, G01N33/49	5/13/2016	/A.F./

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
250	338.4	5/13/2016	/A.F./
	refreshed	10/11/2016	/A.F./

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search	5/13/2016	/A.F./
EAST text search	5/13/2016	/A.F./
Class 250 text search	5/13/2016	/A.F./
Consultation with Yara Green (class 250)	5/17/2016	/A.F./
EAST text search	10/11/2016	/A.F./
Consultation with Yara Green (class 250)	10/14/2016	/A.F./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	claims	10/11/2016	/A.F./
250	338.4	10/11/2016	/A.F./
G01N	G01N3315, G01N1/359, G01N33/49	10/11/2016	/A.F./

/A.F./ Examiner.Art Unit 2884	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

109543 7590 11/09/2016

Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

EXAMINER	
FEIN, ABRA S	

ART UNIT	PAPER NUMBER
2884	

NOTIFICATION DATE	DELIVERY MODE
11/09/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@brookskushman.com

Applicant-Initiated Interview Summary	**Application No.** 14/875,709	**Applicant(s)** ISLAM, MOHAMMED N.	
	Examiner Abra Fein	**Art Unit** 2884	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Abra Fein*.

(2) *Dave Porta*.

(3) *David S. Bir*.

(4)_____.

Date of Interview: *02 November 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *6 and 15*.

Identification of prior art discussed: *Fidler*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Discussed dependent claim 6 and 15 and agreed that Fidler does not sufficiently teach the receiver is configured to be synchronized to the light source. The Applicant suggested they would likely write dependent claims 6 and 15 into independent claims 5 and 14. An additional prior art search will be conducted.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/A. F./ Examiner, Art Unit 2884	/DAVID PORTA/ Supervisory Patent Examiner, Art Unit 2884

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Mohammed N. ISLAM

Group Art Unit: 2884

Examiner: Abra S. Fein

Serial No.: 14/875,709

Filed: October 6, 2015

For: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Attorney Docket No.: OMNI 0105 PUSP1

AMENDMENT UNDER 37 C.F.R. § 1.116 FILED WITH AFCP 2.0 REQUEST

Mail Stop AF
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Final Office Action mailed October 21, 2016, please reconsider and reexamine the application as amended below pursuant to the provisions of the AFCP 2.0 pilot program. A request for consideration under the AFCP 2.0 pilot program is being filed herewith.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A measurement system comprising:

a light source configured to generate an output optical beam, comprising:

one or more semiconductor sources configured to generate an input beam;

one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers; and

one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam;

a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum; and

wherein at least a portion of the output beam broadened spectrum comprises a near-infrared wavelength between approximately 700nm and approximately 2500nm, and wherein at least a portion of the one or more fibers is a fused silica fiber with a core diameter less than approximately 400 microns;

a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam;

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample having a bandwidth of at least 10 nanometers and to generate an output signal; and

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.

2. (Original) The system of Claim 1, wherein the personal device is selected from the group consisting of a smart phone, a tablet, a personal data assistant, a computer, and a microprocessor-based device.

3. (Original) The system of Claim 1, wherein the output signal comprises one or more physiological parameters.

4. (Original) The system of Claim 1, further comprising a remote device configured to receive over the wireless transmission link a received output status comprising the at least a portion of the processed output signal, to buffer the received output status, to process the received output status to generate processed data and to store the processed data.

5. (Currently Amended) A measurement system comprising:

a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,

the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;

an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the receiver is configured to be synchronized to the light source;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and

a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data.

6. (Canceled).

7. (Previously Presented) The system of Claim 5, wherein at least one of the light emitting diodes emits light with a bandwidth between 20 nanometers to 40 nanometers.

8. (Original) The system of Claim 5, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data.

9. (Previously Presented) The system of Claim 5, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode.

10. (Original) The system of Claim 5, wherein the output signal comprises one or more physiological parameters, and the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time.

11. (Previously Presented) The system of Claim 9, wherein the output signal is generated in part by comparing the first and second signals.

12. (Previously Presented) The system of Claim 5, wherein the receiver further comprises one or more filters in front of one of more detectors to select a fraction of the one or more optical wavelengths.

13. (Previously Presented) The system of Claim 5, wherein the output optical beam comprises a plurality of optical wavelengths, and the output signal is generated in part by comparing signals at different optical wavelengths.

14. (Currently Amended) A measurement system comprising:

a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,

the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources; the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample;

the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the wearable measurement device receiver is configured to be synchronize to pulses of the light source;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and

a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

15. (Canceled).

16. (Previously Presented) The system of Claim 14, wherein at least one of the light emitting diodes emits light with a bandwidth between approximately 20 nanometers to approximately 40 nanometers.

17. (Original) The system of Claim 14, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data.

18. (Previously Presented) The system of Claim 14, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode.

19. (Previously Presented) The system of Claim 18, wherein the output signal is generated in part by comparing the first and second signals.

20. (Previously Presented) The system of Claim 14, wherein the receiver further comprises one or more filters in front of one of more detectors to select a fraction of the one or more optical wavelengths.

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Remarks

In the Office Action mailed October 21, 2016, claims 5, 8, 10, 12, 14, 17, and 20 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli et al. (US 2006/0283931 A1) in view of Banet, Rubio Guivernau et al. (US 2014/0078510 A1), and Kleppe et al. (US 2011/0267688 A1). Claims 6-7, 9, 15-16, and 18 are rejected under pre-AIA pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polliand Banet, Rubio Guivernau, and Kleppe, and further in view of Fidler et al. (US 2013/0327966A1). Claims 11, 13, and 19 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli and Banet, Rubio Guivernau, Kleppe, and Fidler, and further in view of Doppke et al. (US 2005/0133691 A1).

Claims 6 and 15 have been canceled without prejudice. Claims 5 and 14 have been amended. Claims 1-5, 7-14, and 16-20 are pending. Reconsideration and re-examination of the application as amended is respectfully requested.

Telephone Interview

Applicant thanks Examiners Fein and Porta for the courtesies extended during the telephone interview on November 2, 2016 to discuss the rejection under 35 U.S.C. §103 with respect to Claims 6 and 15 relative to the disclosure of US 2013/0327966 to Fidler et al. As discussed during the interview, Applicant has incorporated dependent Claim 6 into independent Claim 5, and incorporated dependent Claim 15 into independent Claim 14. The Examiners agreed that Fidler et al. did not disclose the features of dependent Claims 6 and 15, but that an additional search may be performed.

Rejections Under 35 U.S.C. § 103(a)

Claims 5, 8, 10, 12, 14, 17, and 20 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli et al. (US 2006/0283931 A1) in view of Banet, Rubio Guivernau et al. (US 2014/0078510 A1), and Kleppe et al. (US 2011/0267688 A1). Applicant respectfully disagrees and traverses the rejection. Applicant does not necessarily agree or acquiesce to the propriety of the combination of references, or the disclosure or teaching of any of the references as set forth in the rejection. However, Applicant has amended independent claims 5 and 14 in light of the indication of other allowable subject matter and the discussion during the telephonic interview solely to advance prosecution of this application to allowance.

Claims 6-7, 9, 15-16, and 18 are rejected under pre-AIA pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polliand Banet, Rubio Guivernau, and Kleppe, and further in view of Fidler et al. (US 2013/0327966A1). Applicant respectfully disagrees and traverses the rejection. Applicant does not necessarily agree or acquiesce to the propriety of the combination of references, or the disclosure or teaching of any of the references as set forth in the rejection. However, Applicant has amended independent claims 5 and 14 in light of the indication of other allowable subject matter and the discussion during the telephonic interview solely to advance prosecution of this application to allowance The rejection of these claims is believed to be moot in view of the allowance of independent claims 5 and 14 from which these claims depend.

Claims 11, 13, and 19 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Polli and Banet, Rubio Guivernau, Kleppe, and Fidler, and further in view of Doppke et al. (US 2005/0133691 A1). Applicant respectfully disagrees and traverses the rejection. Applicant does not necessarily agree or acquiesce to the propriety of the combination of references, or the disclosure or teaching of any of the references as set forth in the rejection. However, Applicant has amended independent claims 5 and 14 in light of the indication of other allowable subject matter and the discussion during the telephonic interview solely to advance prosecution of this application to allowance. The rejection of these claims is believed to be moot in view of the allowance of independent claims 5 and 14 from which these claims depend.

Summary

Applicant has made a genuine effort to respond to the rejections and advance prosecution of this application. Applicant respectfully submits that all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested.

The Examiner is requested to telephone the undersigned to discuss resolution of any remaining issues.

No additional fee is believed be due as a result of filing this paper. However, please charge any fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 02-3978.

Respectfully submitted,

Mohammed N. ISLAM

By: /David S. Bir/
David S. Bir
Reg. No. 38,383
Attorney/Agent for Applicant

Date: November 17, 2016

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Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
OMNI 0105 PUSP1	14/875709	2015-10-6
First Named Inventor:	**Title:**	
Mohammed N. ISLAM	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:

- Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
- The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
  - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
  - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
    - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
    - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/David S. Bir/	2016-11-17
Name (Print/Typed) David S. Bir	**Practitioner Registration No.** 38383

***Note**: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

[✓] * Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	27547052
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	18-NOV-2016
Filing Date:	06-OCT-2015
Time Stamp:	08:37:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		response.pdf	63887 4619ea61c9961c55042005bb0985be9f492c5983	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:					
Information:					
2	After Final Consideration Program Request	AFCP_2_0.pdf	226594 b87fa1921f967c09437a8703453c8a0f7f3742d3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	290481		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/875,709	Filing Date 10/06/2015	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	11/18/2016	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**0**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
TRACEY BELL

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

109543 7590 01/10/2017
Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

EXAMINER
FEIN, ABRA S

ART UNIT	PAPER NUMBER
2884	

DATE MAILED: 01/10/2017

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

TITLE OF INVENTION: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	04/10/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

109543 7590 01/10/2017
Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

TITLE OF INVENTION: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	04/10/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
FEIN, ABRA S	2884	250-338400

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1_____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2_____ 3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

109543 7590 01/10/2017

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1000 Town Center
Twenty Second Floor
Southfield, MI 48075

EXAMINER	
FEIN, ABRA S	

ART UNIT	PAPER NUMBER
2884	

DATE MAILED: 01/10/2017

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	Examiner	Art Unit	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/18/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-5,7-14 and 16-20*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/A. F./
Examiner, Art Unit 2884

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment

2. The After-Final amendment filed 11/18/2016 has been accepted and entered. Accordingly, Claims 5 and 14 have been amended, and Claims 6 and 15 have been canceled.

3. Claims 1-5, 7-14, and 16-20 are pending in this application.

Response to Arguments

4. Applicant's arguments, see pp.1-3, filed 11/18/2016, with respect to Claims 6 and 15 have been fully considered and are persuasive. Claims 6 and 15 have been written into independent claims 5 and 14. The rejection of claims 5 and 14 has been withdrawn.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 14 (Lines 14-15) – "…wherein the wearable measurement device receiver is configured to be ~~**synchronize**~~ **synchronized** to pulses of the light source…."

Allowable Subject Matter

6. **Claims 1-5, 7-14, and 16-20** are allowed.

7. The following is an examiner's statement of reasons for allowance:

14. Regarding **Claim 1**, Polli et al. (US 2006/0283931, hereinafter Polli) teaches a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductor sources configured to generate an input beam; a measurement apparatus configured to receive a received portion of the output optical beam, which is a delivered portion of the output optical beam; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal wherein at least a portion of the output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 700 nm and approximately 2500 nm [0076; 0013].

Islam (US 2009/0028193, hereinafter Islam) teaches the use of optical amplifiers configured to receive at least a portion of an input beam and to output an intermediate beam from at least one of the one or more optical amplifiers (Abstract).

Buchter et al. (US 8,000,574, hereinafter Buchter) teaches one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least the portion of the intermediate beam to form a first optical beam (col. 8, lines 18-20).

Islam (US 2006/0268393, hereinafter Islam 2) teaches a nonlinear element configured to receive at least a portion of an optical beam and to broaden a spectrum associated with at least a portion of that optical beam through a nonlinear effect in the nonlinear element to form an output optical beam with an output beam broadened spectrum [0039]. Buchter further teacher a supercontinuum radiation source that has a high degree of spatial coherence compared to thermal light sources (col. 1, lines 13-17).

Banet et al. (US 2010/0160798, hereinafter Banet; pub. Jun. 24, 2010) teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link [0005].

Islam (US 2012/0239013, hereinafter Islam 3) teaches a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductor sources configured to generate an input beam; one or more optical amplifiers configured to receive at least a portion of the input beam and to deliver an intermediate beam to an output end of the one or more optical

amplifiers; and one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to form a first optical beam; a nonlinear element configured to receive at least a portion of the first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum (Abstract); and wherein at least a portion of the one or more fibers is a fused silica fiber [0004], a measurement apparatus configured to receive a received portion of the output optical beam and to deliver a delivered portion of the output optical beam to a sample (Fig. 20); and a receiver [0138].

Liu (US 2014/0249427, hereinafter Liu; PCT filed Dec. 15, 2011) teaches a fused silica fiber with a core diameter less than approximately 400 microns [0027].

Although each aspect of the claim is taught individually by multiple references, there is insufficient motivation to render the claim obvious and to combine all seven references. The prior art of record does not disclose or reasonably suggest, along with the other claim limitations, a measurement system comprising: a light source configured to generate an output optical beam, comprising: one or more semiconductors sources, one or more optical amplifiers configured to receive at least a portion of the input beam and to output an intermediate beam from at least one of the one or more optical amplifiers, one or more optical fibers configured to receive at least a portion of the intermediate beam and to communicate at least part of the portion of the intermediate beam to a distal end of the one or more optical fibers to form a first optical beam, and a nonlinear element configured to receive at least a portion of a first optical beam and to broaden a spectrum associated with the at least a portion of the first optical beam to at least 10nm through a nonlinear effect in the nonlinear element to form the output optical beam with an output beam broadened spectrum comprises a short-wave infrared wavelength between approximately 700 nm and approximately 2500 nm; a measurement apparatus configured to receive a received portion of the output optical beam and to deliver to a sample an analysis output beam, which is a delivered portion of the output optical beam and wherein the delivered portion of the output optical beam is a spatially coherent beam; a receiver; and a personal device.

8. Regarding **Claim 5**, Polli teaches a measurement system comprising: a light source comprising: a plurality of semiconductor sources configured to generate an output optical beam; an apparatus configured to receive a received portion of the output optical beam and to deliver an analysis output beam to a sample; a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers [0076; 0013, Polli inherently teaches wavelengths between 700 nanometers and 2500 nanometers since that is the definition of near-infrared]. Polli does not explicitly a personal device and a remote device.

Banet teaches a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link; a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal to process the received output status to generate processed data and to store the processed data [0005], further comprising a light source comprising a plurality of semiconductor source that are light emitting diodes [0043]. Rubio Guivernau et al. (US 2014/0078510, hereinafter Rubio Guivernau; PCT filed May 18, 2012) teaches an apparatus comprising a plurality of lenses configured to receive a portion of the output beam (CLM 9).

Kleppe et al. (US 2011/0267688, hereinafter Kleppe; pub. Nov. 3, 2011) teaches a correlation between a signal-to-noise ratio and pulse rate/light intensity [0115].

The prior art of record does not disclose or reasonably suggest, along with the other claim limitations, a measurement system comprising: a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers, the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of

semiconductor sources; an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample; a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal; a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data, **comprising: namely**, wherein the receiver is configured to be synchronized to the light source. This particular combination is non—obvious to synchronize because the receiver that is synchronized to the light source is also configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, and the light source is configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources. Not only is there not prior art of record that teaches this arrangement, but there is also no motivation to reasonably suggest this.

15. Regarding **Claim 14**, Polli teaches a measurement system comprising: a light source comprising a plurality of semiconductor sources configured to generate an output optical beam; a measurement apparatus configured to receive a received portion of the output optical beam with one or more optical wavelengths, and to deliver an analysis output beam to a sample; and a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal [0076; 0013, Polli inherently teaches wavelengths between 700 nanometers and 2500 nanometers since that is the definition of near-infrared].

Banet teaches wearable measurement device further comprising a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or

knobs, a microprocessor, and a touch screen, the personal device configured to receive and process at least a portion of a signal transmitted over a wireless transmission link; a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data [0005], further comprising a light source comprising a plurality of semiconductor source that are light emitting diodes [0043]. Banet further teaches the benefit of being able to transmit and display information generated [0005]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with a personal device and remote device, as taught by Banet, for the benefit of transmitting and displaying information generated.

Rubio Guivernau teaches an apparatus comprising a plurality of lenses configured to receive a portion of the output beam (CLM 9). Rubio Guivemau further teaches the benefit of optical power efficiency [0049]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with the plurality of lenses configured to receive a portion of the output beam, as taught by Rubio Guivemau, for the benefit of optical power efficiency.

Kleppe teaches a correlation between a signal-to-noise ratio and pulse rate/light intensity [0115]. Kleppe further teaches the benefit of obtaining an optimum detection signal [0115]. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the measurement system, as taught by Polli, with correlation a signal-to-noise ratio with a pulse rate and light intensity, as taught by Kleppe, for the benefit of obtaining an optimum detection signal.

The prior art of record does not disclose or reasonably suggest, along with the other claim limitations, a measurement system comprising: a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers, the light source configured to

increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources; the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample; the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal; a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time, **comprising: namely**, wherein the wearable measurement device receiver is configured to be synchronize to pulsed of the light source. This particular combination is non—obvious to synchronize because the receiver that is synchronized to the light source is also configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, and the light source is configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources. Not only is there not prior art of record that teaches this arrangement, but there is also no motivation to reasonably suggest this.

9. **Claims 2-4, 7-13, and 16-20** are allowable due to dependency.

10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such

submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abra Fein whose telephone number is (571)272-0552. The examiner can normally be reached on Monday-Friday 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID PORTA/
Supervisory Patent Examiner, Art Unit 2884

/A. F./
Examiner, Art Unit 2884

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	Art Unit
	ABRA FEIN	2884

CPC- SEARCHED		
Symbol	Date	Examiner
G01N33/15, G01N21/359, G01N33/49	5/13/2016	/A.F./

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
250	338.4	5/13/2016	/A.F./
	refreshed	10/11/2016	/A.F./
	refreshed	11/23/2016	/A.F./

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search	5/13/2016	/A.F./
EAST text search	5/13/2016	/A.F./
Class 250 text search	5/13/2016	/A.F./
Consultation with Yara Green (class 250)	5/17/2016	/A.F./
EAST text search	10/11/2016	/A.F./
Consultation with Yara Green (class 250)	10/14/2016	/A.F./
EAST text search	11/23/2016	/A.F./
Class 250 text search	11/23/2016	/A.F./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	claims	10/11/2016	/A.F./
250	338.4	10/11/2016	/A.F./

/A.F./ Examiner.Art Unit 2884	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
G01N	G01N3315, G01N1/359, G01N33/49	10/11/2016	/A.F./
	claims	11/23/2016	/A.F./

/A.F./ Examiner.Art Unit 2884	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	**Art Unit**
	ABRA FEIN	2884

CPC						
Symbol					**Type**	**Version**
G01N		33	/	15	F	2013-01-01
A61B		5	/	1455	I	2013-01-01
A61B		5	/	0075	I	2013-01-01
H01S		3	/	302	A	2013-01-01
G01J		3	/	108	I	2013-01-01
G01J		3	/	28	I	2013-01-01
G01J		2003	/	104	A	2013-01-01
G01J		3	/	453	I	2013-01-01
G01N		21	/	359	I	2013-01-01
G01J		3	/	14	A	2013-01-01
G01J		3	/	1838	A	2013-01-01
G01J		2003	/	2826	A	2013-01-01
A61B		5	/	0013	I	2013-01-01
A61B		5	/	0022	I	2013-01-01
A61B		5	/	0086	I	2013-01-01
A61B		5	/	0088	I	2013-01-01
A61B		2562	/	0233	A	2013-01-01
A61B		2562	/	146	A	2013-01-01
A61B		2576	/	02	A	2013-01-01
A61B		5	/	14532	I	2013-01-01
A61B		5	/	14546	I	2013-01-01
A61B		5	/	4547	I	2013-01-01
A61B		2562	/	0238	A	2013-01-01
G01N		33	/	49	I	2013-01-01
G01N		2201	/	061	A	2013-01-01
G01N		2201	/	12	A	2013-01-01
G01N		2201	/	062	A	2013-01-01

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

/A.F./ Examiner.Art Unit 2884 (Assistant Examiner)	11/23/2016 (Date)	**Total Claims Allowed:** 18	
/DAVID PORTA/ Supervisory Patent Examiner.Art Unit 2884 (Primary Examiner)	12/27/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 18

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	**Art Unit**
	ABRA FEIN	2884

/A.F./ Examiner.Art Unit 2884	11/23/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/DAVID PORTA/ Supervisory Patent Examiner.Art Unit 2884	12/27/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	18

U.S. Patent and Trademark Office

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	**Art Unit**
	ABRA FEIN	2884

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
250	338.4	G	0	1	J	5 / 20 (2006.0)						

CROSS REFERENCE(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

/A.F./ Examiner.Art Unit 2884	11/23/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	18	
/DAVID PORTA/ Supervisory Patent Examiner.Art Unit 2884	12/27/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	18

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	**Art Unit**
	ABRA FEIN	2884

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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15	17														
16	18														

/A.F./ Examiner.Art Unit 2884 (Assistant Examiner)	11/23/2016 (Date)	**Total Claims Allowed:** 18	
/DAVID PORTA/ Supervisory Patent Examiner.Art Unit 2884 (Primary Examiner)	12/27/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 18

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	(14/108986).APP.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:07
S2	1029	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:07
S3	269	((Mohammed) near2 (Islam)).INV.	US-PGPUB; USPAT	OR	ON	2015/06/15 12:07
S4	7	(("6885683") or ("6281471") or ("6340806") or ("6301271") or ("7294105") or ("20100046067") or ("20080105665")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:08
S5	52	(("5084880") or ("5180378") or ("5400165") or ("5458122") or ("5617871") or ("5631758") or ("5687734") or ("5696778") or ("5704351") or ("5718234") or ("5748103") or ("5855550") or ("5862803") or ("5847305") or ("5912749") or ("5944659") or ("5957854") or ("6014249") or ("6043927") or ("6289238") or ("6333803") or ("6364834") or ("6381391") or ("6402691") or ("6407853") or ("6441747") or ("6443890") or ("6454705") or ("6480656") or ("6549702") or ("6603910") or ("6659947") or ("6802811") or ("7167300") or ("7209657") or ("7263288") or ("7519253") or ("20020013518") or ("20020019584") or ("20020032468") or ("20020082612") or ("20020109621") or ("20020115914") or ("20020178003") or ("20040174914") or ("20040240037") or ("20050111511") or ("20060245461") or ("20060268393") or ("20070078348") or ("20090028193") or ("20090204110")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:12
S6	4	(("7787503") or ("7800818") or ("8000574") or ("6611643")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:13
S7	82	(("4063106") or ("4158750") or ("4221997") or ("4275266") or ("4374618") or ("4403605") or ("4462080") or ("4516207") or ("4523884") or ("4605080") or ("4641292") or ("4704696") or ("4728974") or ("4762455") or ("4776016") or ("4958910") or	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:19

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S10	2	(("8472108") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 12:54
S11	168	S4 S5 S6 S7 S8 S9 S10	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/15 13:07
S12	2	((12/206432) or (10/652276) or	US-	OR	OFF	2015/06/15

		(10/757341)).APP.	PGPUB; USPAT			14:48
S13	5	(("WOadj2014105520") or ("WOadj2014143276A9") or ("WOadj2014143276") or ("WOadj2013148656") or ("EPadj2831566") or ("WOadj2013148666") or ("EPadj2831565") or ("20130265568") or ("WOadj2014105521") or ("8859969") or ("20130256534") or ("20140236021") or ("CAadj2648549") or ("WOadj2007117867") or ("20060283931") or ("EPadj2011047") or ("EPadj1671094") or ("WOadj2005031302")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/15 14:51
S14	16	WO adj "2014105520" WO adj 2014143276A9 WO adj "2014143276" WO adj "2013148656" EP adj "2831566" WO adj "2013148666" EP adj "2831565" "20130265568" WO adj "2014105521" "8859969" "20130256534" "20140236021" CA adj "2648549" WO adj "2007117867" "20060283931" EP adj "2011047" EP adj "1671094" WO adj "2005031302"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/15 14:51
S15	7	(("6885683") or ("6281471") or ("6340806") or ("6301271") or ("7294105") or ("20100046067") or ("20080105665")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S16	52	(("5084880") or ("5180378") or ("5400165") or ("5458122") or ("5617871") or ("5631758") or ("5687734") or ("5696778") or ("5704351") or ("5718234") or ("5748103") or ("5855550") or ("5862803") or ("5847305") or ("5912749") or ("5944659") or ("5957854") or ("6014249") or ("6043927") or ("6289238") or ("6333803") or ("6364834") or ("6381391") or ("6402691") or ("6407853") or ("6441747") or ("6443890") or ("6454705") or ("6480656") or ("6549702") or ("6603910") or ("6659947") or ("6802811") or ("7167300") or ("7209657") or ("7263288") or ("7519253") or ("20020013518") or ("20020019584") or ("20020032468") or ("20020082612") or ("20020109621") or ("20020115914") or ("20020178003") or ("20040174914") or ("20040240037") or ("20050111511") or ("20060245461") or ("20060268393") or ("20070078348") or ("20090028193") or ("20090204110")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S17	4	(("7787503") or ("7800818") or ("8000574") or ("6611643")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S18	82	(("4063106") or ("4158750") or ("4221997") or ("4275266") or ("4374618") or ("4403605") or	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37

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S19	3	(("6246896") or ("6285897") or ("6847336")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
S20	30	(("5747806") or ("5115673") or ("6512936") or ("6534012") or ("6640117") or ("6788965") or ("6816241") or ("6738652") or ("6587702") or ("6864978") or ("6990364") or ("7010336") or ("7133710") or ("7233816") or ("7299080") or ("7317938") or ("7395158") or ("7519406") or ("7620674") or ("7697966") or ("7787924") or ("8145286") or ("6773922") or ("7807718") or ("20100331637") or ("20110143364") or ("20030022126") or ("20060223032") or ("20100322490") or ("20120013722")).PN.	US-PGPUB; USPAT	OR	OFF	2015/06/16 09:37
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			USPAT; EPO; JPO; DERWENT			
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S26	185	S22 S23 S24 S25	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:37
S27	126	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:44
S28	1	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same semiconductor same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:46
S29	24	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconductor and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:47
S30	24	S26 and ((light near2 source)(near-infrared near-IR IR infrared NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconduct$5 and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:47

S31	21	S26 and ((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) and semiconduct$5 and(multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 09:48
S32	648	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same semiconduct$5 same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:05
S33	123	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:08
S34	5	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:37
S35	6	S25 and (semiconduct$5 multiplex$5)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:50
S36	2	S25 and (multiplex$5)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:50
S37	6	S25 and (semiconduct$5 multiplex$5 mux)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:51
S38	8	S25 and (laser (super near luminesc$5 near diode)LED (light near emit$5 near diode))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:53
S39	9	S25 and (fiber)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:54
S40	1	S25 and (FTIR)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:56
S41	4	S25 and (fourier)	US-PGPUB; USPAT;	OR	ON	2015/06/16 10:59

			EPO; JPO; DERWENT			
S42	4	S25 and (fourier with (IR infrared infra-red))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:59
S43	4	S25 and (fourier near4 (IR infrared infra-red))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 10:59
S44	575	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:21
S45	8428	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:21
S46	3	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 11:22
S47	59	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:07
S48	4	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:08
S49	23	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S50	2	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S51	23	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12
S52	7	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)same fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:12

S53	115	S26 and fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S54	43	S26 and(fiber with beam)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S55	2	S26 and(fiber with beam)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:14
S56	9	S26 and(FTIR FT-IR ("fourier transform infrared"))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/16 13:20
S57	270	((Mohammed) near2 (Islam)).INV.	US-PGPUB; USPAT	OR	ON	2015/06/16 13:22
S58	67	S57 and multiplexer.clm.	US-PGPUB; USPAT	OR	ON	2015/06/16 13:22
S59	21	S57 and ((multiplexer and semiconductor and fibers).clm.)	US-PGPUB; USPAT	OR	ON	2015/06/16 13:23
S60	2	S57 and ((multiplexer and semiconductor and fibers and FTIR).clm.)	US-PGPUB; USPAT	OR	ON	2015/06/16 13:23
S61	125	S57 and (broaden$5)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S62	64	S57 and (broaden$5 with (nonlinear non-linear))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S63	29	S57 and (broaden$5 with (nonlinear non-linear) with spectrum)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S64	9	S57 and (broaden$5 near4(nonlinear non-linear) with spectrum)	US-PGPUB; USPAT	OR	ON	2015/06/16 16:17
S65	2	S57 and (organic with (overtone (combination$5 absor%8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:31
S66	2	S57 and (organic with (overtone (combination$5 near absor$8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:32
S67	206	(organic with (overtone (combination$5 near absor$8)))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:32
S68	62	(organic with (overtone))	US-PGPUB; USPAT	OR	ON	2015/06/16 16:40
S69	14	(organic with (overtone))and "250".clas.	US-PGPUB;	OR	ON	2015/06/16 16:40

			USPAT			
S70	1	("6105823").PN.	US-PGPUB; USPAT	OR	OFF	2015/06/17 16:05
S71	320	abrahamsson.in.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/17 16:05
S72	4	abrahamsson.in. and multiplexer	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/06/17 16:06
S73	1034	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2015/07/23 13:49
S74	5	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)same sample	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:49
S75	2	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband) and fiber and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S76	125	((light near2 source)(near-infrared near-IR NIR)SWIR(super near continuum super-continuum supercontinuum) SC (short near wave near infrared)(short near wave near IR)) same (semiconduct$5 with amplif$6)same fiber same (multiplexer multiplexor)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S77	8	(multiplexer multiplexor) same (pharmaceutical counterfeit illicit contraband)same fiber	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/23 13:50
S78	14	(organic with (overtone))and "250".clas.	US-PGPUB; USPAT	OR	ON	2015/07/23 13:50
S79	1	(sample) with (overtone or "combinational absorption band") with(wavelength near range) .clm.	US-PGPUB; USPAT	OR	ON	2015/07/23 13:53
S81	7	250/338.4 and @pd>"20150625"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2015/07/24 11:51
S89	1	("20100161794").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/13 11:39
S90	606	banet.in.	US-PGPUB; USPAT; EPO; JPO;	OR	ON	2016/05/13 11:40

			DERWENT			
S91	5	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/05/13 11:58
S92	0	S91 and (LED light near emit$7 near diode) with puls$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:58
S93	93	(near-infrared near-IR)with(LED light near emit$7 near diode) with puls$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:59
S94	8	(near-infrared near-IR)with(LED light near emit$7 near diode) with puls$5 and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/05/13 11:59
S95	1059	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/05/13 13:56
S96	1	("9164032").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/17 14:53
S97	1	("0612310").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/17 15:31
S98	1	("20140249427").PN.	US-PGPUB; USPAT	OR	OFF	2016/05/17 15:32
S99	1067	(250/338.4).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/10/11 11:38
S100	0	(light near source) with increas$4 near2 signal$to$noise near ratio with light near intensit$4 with semiconduct$4 with pulse near2 rate	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:39
S101	0	(light near source) with increas$4 near2 signal$to$noise near ratio with light near intensit$4 with semiconduct$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:40
S102	0	(light near source) with increas$4 near2 "signal to noise" near ratio with light near intensit$4 with semiconduct$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:40
S103	0	(light near source) with increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:57
S104	0	(light) with increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58

S105	0	(source) with increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58
S106	0	increas$4 near2 "signal to noise" near ratio with light near intensit$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58
S107	136	increas$4 near2 "signal to noise" near ratio	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:58
S108	0	increas$4 near2 "signal to noise" near ratio with (increas$4 near2 light near intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:59
S109	0	increas$4 near2 "signal to noise" near ratio with (light near intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:59
S110	1	increas$4 near2 "signal to noise" near ratio with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 11:59
S111	31	"signal to noise" near ratio with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:04
S112	1	increas$4 near4 "signal to noise" near ratio with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:05
S113	1	(increas$4 near4 "signal to noise ratio") with (intensit$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:06
S114	0	(increas$4 near4 "signal to noise ratio") with (pulse near rate)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:06
S115	10	(increas$4 near4 (signal near2 noise near ratio)) with (pulse near rate)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:06
S116	2	(increas$4 near4 (signal near2 noise near ratio)) with increas$4 near2(pulse near rate)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 12:07

S117	7	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$ or US-20090244288-$ or US-20140249427-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/10/11 13:22
S118	5	S117 and (lens lenses)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:22
S119	1	S117 and ((lens lenses)with sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:23
S120	1	S117 and ((lenses)with sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:24
S121	0	S117 and ((plurality near2 lenses)with sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:25
S122	3	((plurality near2 lenses)with (output near2 beam) near4 sample)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 13:25
S123	491	(G01N33/15.cpc. G01N21/359.cpc. G01N33/49.cpc.)and @pd>"20160513"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 14:02
S132	1	("8180422").PN.	US-PGPUB; USPAT	OR	OFF	2016/10/11 14:45
S133	19	(("8180422") or ("7771320") or ("6619835") or ("9326712") or ("5267152") or ("7356364") or ("5246004") or ("8472108") or ("20100217102") or ("20120310062") or ("20120316455") or ("20140275854") or ("20140275852") or ("20160045118") or ("20110208015") or ("20110040197") or ("20070021670") or ("20110282167") or ("20130274569")).PN.	US-PGPUB; USPAT	OR	OFF	2016/10/11 14:48
S134	0	S133 and signal adj to adj noise near2 ratio	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/11 14:49
S135	1	("20110267688").PN.	US-PGPUB; USPAT	OR	OFF	2016/10/14 16:53
S136	348	((light adj emit$5 adj diode) LED)near4 bandwidth near4 (nm nanometer)	US-PGPUB; USPAT; EPO; JPO;	OR	ON	2016/10/14 17:14

			DERWENT			
S137	2	((light adj emit$5 adj diode) LED)near4 bandwidth near4 (nm nanometer) with wireless	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/14 17:14
S138	23	((light adj emit$5 adj diode) LED)near4 bandwidth near4 (nm nanometer) and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/14 17:15
S139	3214	((light adj emit$5 adj diode) LED near second)with (second near2 signal)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/14 17:31
S140	1880	((light adj emit$5 adj diode) LED near second)with (second near2 signal) same ((light adj emit$5 adj diode) LED near first)with (first near2 signal)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/14 17:32
S141	76	((light adj emit$5 adj diode) LED near second)with (second near2 signal) same ((light adj emit$5 adj diode) LED near first)with (first near2 signal)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/14 17:32
S142	70	((light adj emit$5 adj diode) LED near second)with (second near2 signal) with ((light adj emit$5 adj diode) LED near first)with (first near2 signal)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/14 17:33
S143	1	((light adj emit$5 adj diode) LED near second)with (second near2 signal) with ((light adj emit$5 adj diode) LED near first)with (first near2 signal)same distance and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 20:57
S144	1	((light adj emit$5 adj diode) LED near second)with (second near2 signal) with ((light adj emit$5 adj diode) LED near first)with (first near2 signal)with distance and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 20:58
S145	84	(output near signal)with generat$4 with compar$5 near4 (first near2 second near2 signals)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 21:36
S146	28	(output near signal)near4 generat$4 near4 compar$5 near4 (first near2 second near2 signals)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 21:37
S147	11	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$ or US-20090244288-$ or US-20140249427-$ or US-20140078510-$ or US-20110267688-$ or US-20130327966-$ or US-20050133691-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/10/16 21:58
S148	8	S147 and filter	US-PGPUB;	OR	ON	2016/10/16 21:58

			USPAT; EPO; JPO; DERWENT			
S149	4	S147 and filter with detect$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 21:58
S150	0	(output near signal)near4 generat$4 near4 compar$5 near4 (first near2 second near2 signals)with (different near2 optical near wavelength)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:16
S151	0	(output near signal)near4 generat$4 near4 compar$5 near4 (first near2 second near2 signals)with (different near2 optical near wavelength)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:16
S152	0	(output near signal)near4 generat$4 near4 compar$5 near4 (first near2 second near2 signals)same(different near2 optical near wavelength)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:19
S153	0	(output near signal)near4 generat$4 near4 compar$5 near4 (first near2 second near2 signals)same(optical near wavelength)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:19
S154	0	(output near signal) near4 compar$5 near4 (first near2 second near2 signals)with (different near2 optical near wavelength)and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:22
S155	0	(output near signal) near4 compar$5 near4 (first near2 second near2 signals)with (different near2 optical near wavelength)same (differen$4 near2 wavelength)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:22
S156	7	(output near signal) near4 compar$5 near4 (first near2 second near2 signals)same(optical near wavelength)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/10/16 22:22
S157	1	("20120239013").PN.	US-PGPUB; USPAT	OR	OFF	2016/10/17 12:51
S158	12	(US-20060283931-$ or US-20090028193-$ or US-20100160798-$ or US-20090244288-$ or US-20140249427-$ or US-20140078510-$ or US-20110267688-$ or US-20130327966-$ or US-20050133691-$ or US-20120239013-$).did. or (US-8000574-$ or US-6181414-$).did.	US-PGPUB; USPAT	OR	ON	2016/11/02 09:32
S159	5	S158 and synchroniz$6	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/02 09:33
S160	1067	(250/338.4).CCLS.	US-	OR	OFF	2016/11/23

			PGPUB; USPAT			12:53
S161	885	synchroniz$6 near6 (light near2 source) with receiv$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:36
S162	192	synchroniz$6 near6 (light near2 source) with receiv$4 .clm.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:37
S163	0	semiconduct$4 same synchroniz$6 near6 (light near2 source) with receiv$4 with reflect$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:38
S164	789	((light near source)(LED (light adj emit$5 adj diode)))near6 synchroniz$5 near6 receiv$5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:40
S165	0	((light near source)(LED (light adj emit$5 adj diode)))near6 synchroniz$5 near6 receiv$5 near4 reflect$4 and "250".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:40
S166	42	((light near source)(LED (light adj emit$5 adj diode)))near6 synchroniz$5 near6 receiv$5 near4 reflect$4	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:41
S167	6	((light near source)(LED (light adj emit$5 adj diode)))near6 synchroniz$5 near6 receiv$5 near4 reflect$4 with (output)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2016/11/23 13:41

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S80	0	(sample) with (overtone or "combinational absorption band") with(wavelength near range) .clm.	USPAT	OR	ON	2015/07/23 13:53
S82	7	250/338.4 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:51
S83	47202	G01N|21/35 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:51
S84	54478	A61B|5/1455 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:51
S86	54480	A61B|5/0075 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:52
S87	9513	H01S|3/302 and @pd>"20150625"	USPAT	OR	ON	2015/07/24 11:52
S88	0	(S82 S83 S84 S86 S87)and (non-destructive with non-contact with measur$5) with deliver$5.clm.	USPAT	OR	ON	2015/07/24 11:54

S128	71	(G01N33/15.cpc. G01N21/359.cpc. G01N33/49.cpc.)and @pd>"20160513"	USPAT	OR	ON	2016/10/11 14:02
S130	45	250/338.4 and @pd>"20160513"	USPAT	OR	ON	2016/10/11 14:02
S131	0	(increas$4 near4 (signal near2 noise near ratio)) with increas$4 near2(pulse near rate).clm.	USPAT	OR	ON	2016/10/11 14:35
S168	105	synchroniz$6 near6 (light near2 source) with receiv$4 .clm.	USPAT	OR	ON	2016/11/23 13:37
S169	13	synchroniz$6 near6 (light near2 source) with receiv$4 with reflect$4 .clm.	USPAT	OR	ON	2016/11/23 13:37
S170	0	semiconduct$4 same synchroniz$6 near6 (light near2 source) with receiv$4 with reflect$4 .clm.	USPAT	OR	ON	2016/11/23 13:38

11/23/2016 2:41:53 PM
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14875709	ISLAM, MOHAMMED N.
	Examiner	**Art Unit**
	ABRA FEIN	2884

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/13/2016	10/11/2016	11/23/2016						
1	1	✓	=	=						
2	2	✓	=	=						
3	3	✓	=	=						
4	4	✓	=	=						
5	5	✓	✓	=						
	6	✓	✓	-						
6	7	✓	✓	=						
7	8	✓	✓	=						
8	9	✓	✓	=						
10	10	✓	✓	=						
9	11	✓	✓	=						
11	12	✓	✓	=						
12	13	✓	✓	=						
13	14	✓	✓	=						
	15	✓	✓	-						
14	16	✓	✓	=						
15	17	✓	✓	=						
16	18	✓	✓	=						
17	19	✓	✓	=						
18	20	✓	✓	=						

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

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	1	20060058683	A1	2006-03-16	Chance	
	2	20160327476	A1	2016-11-10	ISLAM	

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	1	101849821	CN	B	2013-07-04	Univ Huazhong Science Tech	See EP Search Report cited below	
	2	2012135952	WO	A1	2012-10-11	The Governing Council Of The University Of Toronto	See EP Search Report cited below	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14875709
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	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
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	1	Extended European Search Report for European Application No. 17156625.0 dated March 20, 2017	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2017-03-28
Name/Print	David S. Bir	Registration Number	38383

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Electronic Patent Application Fee Transmittal

Application Number:	14875709
Filing Date:	06-Oct-2015
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Filer:	David S. Bir/Pamela Demos
Attorney Docket Number:	OMNI 0105 PUSP1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt	
EFS ID:	28760998
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	28-MAR-2017
Filing Date:	06-OCT-2015
Time Stamp:	18:41:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$90
RAM confirmation Number	032917INTEFSW00005755023978
Deposit Account	023978
Authorized User	David Bir
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	CN101849821B_w_English_Abstract.pdf	803948 79c77a191bc5fea399dce69b1ee6ca0b8191b948	no	11
Warnings:					
Information:					
2	Foreign Reference	WO2012135952A1.pdf	6794485 eb8aaf1878815c6629286e4ec2f6599795839123	no	85
Warnings:					
Information:					
3	Non Patent Literature	EP_Extended_Search_Report.pdf	302980 8ea49d8e22aaba43ee5a22d4102e7806b24f69b4	no	9
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New International Application Filed with the USPTO as a Receiving Office
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Bibliographic data: CN101849821 (B) — 2012-07-04

Optical fiber near-infrared spectrometer

Inventor(s): HUI GONG; YONG HE; QINGMING LUO; ZHONGXING ZHANG ± (GONG HUI, ; HE YONG, ; LUO QINGMING, ; ZHANG ZHONGXING)

Applicant(s): UNIV HUAZHONG SCIENCE TECH ± (HUAZHONG UNIVERSITY OF SCIENCE & TECHNOLOGY)

Classification: **- international:** ***A61B5/026***
- cooperative:

Application number: CN20101200035 20100613 Global Dossier

Priority number (s): CN20101200035 20100613

Also published as: CN101849821 (A)

Abstract of CN101849821 (B)

The invention relates to an optical fiber near-infrared spectrometer in the technical field of medical devices. The optical fiber near-infrared spectrometer uses multi-tail optical fiber collimator as light source optical fiber, uses a number lock technology as a technical scheme for weak signal extraction, uses a laser diode with a PD as a light source for sinusoidal modulation, uses an avalanche photodiode (APD) or photomultiplier tube (PMT) as a detector, and uses thick core-diameter plastic optical fiber, liquid-core optical fiber, silica optical fiber, a silica optical fiber bundle or glass optical fiber bundle as detection optical fiber.; The invention has the advantages that the instrument can conduct nondestructive real-time hemodynamic parameter detection to biological tissues sheltered by hairs, the noise level of the instrument is low, the time resolution is high, the stability is high, the price is cheap, the hardware circuit design is greatly simplified and the portabilityof the instrument is realized.

IPR2025-01250 Page 00818

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审查员 陈淑珍

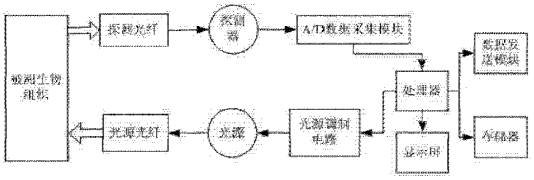
权利要求书 1 页 说明书 6 页 附图 2 页

(54)发明名称

一种光纤近红外光谱检测仪

(57)摘要

本发明涉及医疗设备技术领域的光纤近红外光谱检测仪，它以多尾纤光纤准直器作为光源光纤，采用数字锁定技术作为微弱信号提取技术方案，以带有PD的激光二极管作为光源进行正弦调制，以雪崩光电二极管APD或光电倍增管PMT作为探测器，以粗芯径塑料光纤、液芯光纤、石英光纤、石英光纤束或玻璃光纤束作为探测光纤。该仪器对即使有毛发遮挡的生物组织也可进行无损实时的血液动力学参数检测，仪器噪声水平低，时间分辨率高，稳定性高，价格便宜，大大简化硬件电路设计，实现了仪器的便携化。



CN 101849821 B

1. 一种近红外光谱检测仪，包括光源，光源光纤，探测光纤，探测器，光源调制电路，A/D 数据采集模块和处理器，其特征在于，所述光源光纤为多尾纤光纤准直器，以实现将多个波长的入射光通过不同的尾纤传输到准直器准直透镜的焦点处，从焦点处出射的光经透镜后以平行光均匀入射生物组织。

2. 根据权利要求 1 所述的近红外光谱检测仪，其特征在于，还包括数字锁定放大器，所述数字锁定放大器连接所述 A/D 数据采集模块，用于对探测光纤采集到的 10pW 至 nW 级微弱信号进行数字化锁定放大提取。

3. 根据权利要求 2 所述的近红外光谱检测仪，其特征在于，所述数字锁定放大器的功能由处理器或者另外的计算机实现。

4. 根据权利要求 3 所述的近红外光谱检测仪，其特征在于，所述光源为带有 PD 的激光二极管，以实现对光源的正弦调制，产生正弦光信号。

5. 根据权利要求 4 所述的近红外光谱检测仪，其特征在于，所述探测光纤为粗芯径塑料光纤，其直径为 1mm 至 3.5mm。

6. 根据权利要求 5 所述的近红外光谱检测仪，其特征在于，所述探测器为高探测灵敏度、低噪声水平、带有前置放大功能的雪崩光电二极管 APD 或高探测灵敏度、低噪声水平、带有前置放大功能的光电倍增管 PMT，以实现对 pW 级微弱光信号的探测。

7. 根据权利要求 6 所述的近红外光谱检测仪，其特征在于，它还包括存储器，所述存储器连接所述处理器，接收并存储生理参数变化信息。

8. 根据权利要求 7 所述的近红外光谱检测仪，其特征在于，还包括显示屏，所述显示屏连接所述处理器，接收并显示所述生理参数变化信息。

9. 根据权利要求 8 所述的近红外光谱检测仪，其特征在于，还包括数据发送模块，所述数据发送模块连接所述处理器，所述处理器通过所述数据发送模块将所述生理参数变化信息传输给外部 PC 机，以供外部 PC 机进行离线分析。

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一种光纤近红外光谱检测仪

技术领域

[0001] 本发明涉及医疗设备技术领域的光纤近红外光谱检测仪。

背景技术

[0002] 近红外光谱术是近 20 年来发展起来的一种非侵入式测量血液动力学参数变化的光学成像技术。生物组织对波长为 600~900nm 的近红外光存在低吸收、高散射的特性，因此这一波段的光可以穿透生物组织几个厘米的厚度而对深层生物组织进行探测。近红外光谱术根据成像原理的不同，又可以分为连续光技术、频域调制技术和时间分辨技术。其中，基于修正的 Beer-Lambert 吸收定律的连续光近红外光谱术具有时间分辨率高、测量过程中受运动限制少、成本低、可实现便携化等优势，是目前应用最为广泛的近红外光谱测量技术。

[0003] 目前国内外已有多个便携式近红外检测仪的专利和研制文章报道，国外已有商用产品被广泛应用在脑功能研究、运动肌氧检测、乳腺癌检测等领域。比如，国内公开号 CN101002673A，CN1223858C，CN1540314A，CN1239125C 的仪器；美国 NIM 公司的 Micro-RunMan 仪器，Somanetics 公司的 INVOS 5100 仪器，日本 OMRON 公司的 HEO-200 仪器，意大利 NIROX 公司的 NIMO 仪器等。这些仪器的光源和探测器均是直接与被测生物组织接触，在满足激光安全标准的前提下，以增大光源出光面积进而增大入射生物组织的光功率(最高可达几十毫瓦)。相对较高的入射光功率和较大的探测器光敏面使得这些仪器能够获得较高的信噪比。因此，这些仪器的探头、后续信号处理电路的设计都较易实现，也较易实现便携化。但是，这些仪器由于受探头光源出光面和探测器光敏面尺寸的限制，仅能对没有浓密毛发遮挡的生物组织，如人脑前额叶，肌肉组织，乳房等进行检测，黑色毛发对光的吸收导致这些仪器无法对有头发遮挡的生物组织，如人脑顶叶，枕叶等脑区进行检测，这就使这些仪器的应用范围受到了限制。

[0004] 为了扩大近红外检测仪的应用范围，实现对有毛发遮挡的生物组织的检测，目前国外已有一些公司研制出采用光纤探头的近红外脑功能成像仪。比如，日本日立公司的 ETG-100、ETG-4000、ETG-7000 产品，岛津公司的 OMM-2000、OMM-3000 产品，美国 NIRx 公司的 DYNOT 仪器等。这些仪器光源发出的光先耦合进光纤束，光纤束的出光端与大脑头皮接触将光射入大脑，探测光纤束接收经过大脑吸收和散射后的出射光，并传输给探测器。光纤由于截面小，可以放置在头发间隙中与头皮接触，因此光纤的设计优化了出光面和接光面的面积，从而可以对有头发遮挡的脑区进行探测。为了满足激光安全标准的限制，光源的入射光功率一般只有几 mW。入射光功率的减弱，探测光纤接光面积的变小，导致探测器能接收到的信号非常微弱，一般仅为 10pW 至 nW 量级，因此，这些仪器在设计上对后续弱信号处理硬件电路设计要求非常高，电路设计复杂，一般均采用模拟锁定放大阵列来实现对弱信号的提取，这就导致整个仪器体积庞大，无法实现便携。此外，这些仪器均采用光纤束作为光源光纤和探测光纤，但是众所周知，光纤束不仅存在填充比损耗，而且在频繁使用过程中，极易出现内部单丝折断破损，从而导致光纤传光效率下降，传光不均，并且光纤束造价

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昂贵，成本高。因此，这些仪器一般应用在医院内部临床脑功能疾病的检测。

[0005] 对于很多脑功能研究者来说，比如对于认知神经科学研究者来说，他们往往希望能够在真实的生活环境中对人的大脑进行无损检测，以研究大脑的认知活动过程或对脑精神疾病进行检测，这就要求光纤近红外脑功能成像仪尽可能做到便携化，光纤也需要具有不易破损，耐用性高，成本低廉的特点。上述国外的光纤近红外脑功能成像仪，由于受体积和成本的限制，是无法满足认知神经科学研究这一需求的。

发明内容

[0006] 针对目前近红外检测仪器存在的不足，本发明所要解决的问题是提供一种近红外检测仪，该仪器对即使有毛发遮挡的生物组织也可进行无损实时的血液动力学参数检测，并且仪器噪声水平低，时间分辨率高，稳定性高，光纤不易破损，传光均匀，价格便宜，大大简化微弱信号提取的硬件电路设计，真正实现便携化。

[0007] 为解决上述技术问题，本发明提出一种采用数字锁定放大技术的便携式近红外检测仪，包括光源，光源光纤，探测光纤，探测器，光源调制电路，A/D 数据采集模块，处理器，显示屏，存储器和数据发送模块。所述处理器向所述光源调制电路发出控制指令，所述光源调制电路对所述各波长光源分别进行正弦调制发光，所述光源调制电路调节所述光源的正弦发光频率和发光功率，所述光源发出的正弦波光耦合进所述光源光纤，经光源光纤传输入射生物组织，所述探测光纤一端接收经过生物组织吸收和散射后的后向散射光子，并将光子传输给探测光纤另外一端耦合的所述探测器，探测器将接收到的光信号转换为电压信号，并对电压信号进行前置放大后发送到所述 A/D 数据采集模块，所述 A/D 数据采集模块将模拟电压信号转换为数字信号，并将数字信号发送给所述处理器，所述处理器用于对信号进行数字锁定放大提取信号幅值信息，以得到光强变化信息，并通过算法将所述光强变化信息转换成各种生理参数的变化信息，所述显示屏连接所述处理器以显示各种生理参数的变化过程，所述存储器连接所述处理器，对数据进行存储，所述数据发送模块连接所述处理器，可以将各种生理参数的变化信息发送给其他处理器进行离线数据分析；其特征在于，本发明所采用的光源光纤优先选用多尾纤光纤准直器，以实现将多个波长的入射光通过不同的尾纤传输到准直器准直透镜的焦点处，从焦点处出射的光经透镜后以平行光均匀入射生物组织。该设计既可以实现多个波长入射光同时从同一位置均匀入射生物组织，又可以省去传统光纤近红外检测仪光源光纤设计中采用的光纤切换开关和波分复用器，大大简化了系统设计，便于实现系统的便携化。

[0008] 光源光纤设计中选用的光纤准直器的尾纤是普通的多模光纤，准直器前端的准直透镜对从多模光纤传输至透镜焦点处的入射光束进行扩束，从而实现入射光的均匀入射。与传统光纤近红外检测仪的光源光纤采用光纤束的设计相比，该设计可以克服光纤束易出现单丝折断而导致入射生物组织的光不均匀的缺点，并且大大降低了成本。

[0009] 进一步改进的，本发明还包括数字锁定放大器，所述数字锁定放大器连接所述 A/D 数据采集模块，用于对探测光纤采集模块采集到的 10pW 至 nW 级微弱信号进行数字化锁定放大提取。

[0010] 所述数字锁定放大器的功能由处理器或者另外的计算机实现。更具体来说，设输入的模拟信号源为：

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[0011]

$$S(t)=dc_s+A_s\cos(2\pi f_m t+\phi_s) \quad \cdots\cdots (2)$$

[0012] 其中 A_s 为信号幅度，f_s 为信号初相位，f_m 为信号频率。假设以 f_s 采样频率对信号进行采样 N_s 个点，可以产生离散信号：

[0013] $$M[n]=dc_m+A_m\cos[\frac{2\pi f_m n}{f_s}+\phi],0\le n\le N_s-1 \quad \cdots\cdots (3)$$

[0014] 处理器内部生成的正弦和余弦参考信号为：

[0015] $$C[n]=\cos[\frac{2\pi f_m n}{f_s}] \quad \cdots\cdots (4)$$

[0016] $$S[n]=\sin[\frac{2\pi f_m n}{f_s}] \quad \cdots\cdots (5)$$

[0017] 离散的参考信号与离散的测量信号相乘，展开以后就得到：

[0018] $$I[n]=M[n]\times\cos[\frac{2\pi f_m n}{f_s}] \quad \cdots\cdots (6)$$

[0019] $$I[n]=\frac{1}{2}A_s\cos(\phi_m)+dc_m\cos[\frac{2\pi f_m n}{f_s}]+\frac{1}{2}A_s\cos[\frac{4\pi f_m n}{f_s}+\phi_m] \quad \cdots\cdots (7)$$

[0020] $$Q[n]=M[n]\times\sin[\frac{2\pi f_m n}{f_s}] \quad \cdots\cdots (8)$$

[0021] $$Q[n]=\frac{1}{2}A_s\sin(\phi_m)+dc_m\sin[\frac{2\pi f_m n}{f_s}]+\frac{1}{2}A_s\sin[\frac{4\pi f_m n}{f_s}+\phi_m] \quad \cdots\cdots (9)$$

[0022] I[n] 和 Q[n] 中的第一项是只含有信号幅值和相位信息的直流成分，对 I[n] 和 Q[n] 进行低通滤波，去除交流成分，只保留直流成分，则得到：

[0023]

$$X[n]\approx\frac{1}{2}A_m\cos(\varphi_m) \quad \cdots\cdots (10)$$

[0024]

$$Y[n]\approx\frac{1}{2}A_m\sin(\varphi_m) \quad \cdots\cdots (11)$$

[0025] 最后进行下面的运算就可以得到下面的幅度信号：

[0026]

$$A_m=2\times\sqrt{X^2+Y^2} \quad \cdots\cdots (12)$$

[0027] 相对于模拟锁定放大器，数字锁定放大器在设计上简化了模拟器件的使用，不仅适合于便携式仪器的设计，还可以避免直流放大器使用所引入的直流漂移、温漂、非线性误差和增益误差，因此具有更高的微弱信号提取能力。数字锁定放大器相关运算的数据点数（相对于模拟积分时间常数）和低通滤波器的参数可以根据信号特点的不同而随时进行调节，具有更高的设计灵活性。

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[0028] 本发明中，数字锁定运算需要的正弦和余弦参考信号优选方案为由处理器内部数字合成或者另外的计算机合成处理，这样可以保证两路参考信号同频且初始相位相差 90 度的绝对正交，参考信号不会受到外界噪声干扰。

[0029] 所述探测光纤可以是粗芯径的塑料光纤、液芯光纤、石英光纤中的一种，也可以是石英光纤束和玻璃光纤束。本发明中，优选方案为粗芯径塑料光纤，其直径为 1mm 至 3.5mm，因为与传统采用光纤束作为探测光纤的设计相比，粗芯径塑料光纤在实现大数值孔径的同时，不存在光纤束设计中具有填充比损耗的问题，而且，可以克服光纤束的光纤单丝易折断从而导致传光效率下降的问题，并且大大降低了成本。

[0030] 本发明所采用的光源优选为带有 PD 的激光二极管，以实现对光源的正弦调制，产生正弦光信号。光源波长范围为 600~1000nm。但是本发明的光源不仅仅限于激光二极管，也可以是其他可实现正弦调制的近红外光源，如集成近红外激光光源模块。

[0031] 本发明所采用的探测器为高探测灵敏度、低噪声水平、带有前置放大功能的雪崩光电二极管 APD 或光电倍增管 PMT，以实现对 pW 级微弱光信号的探测。但是，如有其他光电探测器，在光源波长范围内满足高探测灵敏度、低噪声水平的要求，也可以作为本发明的探测器。

[0032] 所述处理器，可以是嵌入式微处理器，也可以是计算机 CPU。

[0033] 所述处理器，当探测通道增多时，为了保证足够高的时间分辨率，需要提高数字锁定运算的速度，此时处理器可以是计算机集群或者图形处理器 GPU，以实现对数据的并行加速处理。

[0034] 作为优选，本发明还包括存储器，所述存储器连接所述处理器，接收并存储所述生理参数变化信息。

[0035] 作为又一优选，本发明还包括显示屏，所述显示屏连接所述处理器，接收并显示所述生理参数变化信息。

[0036] 作为还一优选，本发明还包括数据发送模块，所述数据发送模块连接所述处理器，所述处理器通过所述数据发送模块将所述生理参数变化信息传输给外部 PC 机，以供所述外部 PC 机进行离线分析，数据发送模块的数据发送方式可以是有线数据传输方式，也可以是无线数据传输方式。

[0037] 本发明采用数字锁定技术作为微弱信号提取的技术方案，以带有 PD 的激光二极管作为光源进行正弦调制，以多尾纤光纤准直器作为光源光纤，以雪崩光电二极管 APD 或光电倍增管 PMT 作为探测器，以粗芯径塑料光纤、液芯光纤、石英光纤、石英光纤束或玻璃光纤束作为探测光纤，设计了一种基于光纤探头的便携式近红外检测仪，该仪器对即使有毛发遮挡的生物组织也可进行无损实时的血液动力学参数检测，仪器噪声水平低，时间分辨率高，稳定性高，价格便宜，大大简化硬件电路设计，实现了仪器的便携化。

附图说明

[0038] 下面结合附图和具体实施方式对本发明的技术方案作进一步具体说明。

[0039] 图 1 为一种便携式光纤近红外检测仪的结构框图。

[0040] 图 2 为本发明实施案例之一基于 PC 机的便携式光纤近红外检测仪的结构框图。

[0041] 图 3 为本发明实施案例之一基于 PC 机的便携式光纤近红外检测仪应用于在体前

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臂阻断实验结果图。

具体实施方式

[0042] 便携式光纤近红外检测仪的结构框图如图 1 所示。处理器向光源调制电路发出控制指令，使光源调制电路对光源进行正弦调制发光，光源的正弦发光频率和发光功率均可由光源调制电路进行控制。光源发出的正弦光耦合入光源光纤，经光源光纤传输入射被测生物组织。在被测生物组织表面与光源光纤同侧间隔几厘米距离处放置的探测光纤接收经过生物组织吸收和散射后的后向散射光子，探测光纤将接收的光子传输给探测光纤另外一端耦合的探测器。探测器将接收到的光信号转换为电压信号，并对电压信号进行前置放大后发送到 A/D 数据采集模块。A/D 数据采集模块将模拟电压信号转换为数字信号，并将数字信号发送给处理器。处理器对信号进行数字锁定运算以提取信号幅值信息，即光强变化信息。在处理器内部，光强变化信息再通过修正的 Beer-Lambert 吸收定律转换成血液动力学参数等生理参数的变化信息。然后处理器将生理参数的变化传输到显示屏和存储器进行显示和存储。处理器也可以选择将生理参数变化信息通过数据发送模块发送给其他处理器进行离线数据分析。

[0043] 图 2 所示为本发明实施案例之一，基于 PC 机的便携式光纤近红外检测仪的结构框图。PC 机向下位机微处理器 AT89C2051 发送工作指令，AT89C2051 向直接数字合成正弦波发生芯片 ML2035 发送 16 位频率编码指令，使正弦波发生芯片 ML2035 开始产生特定频率的正弦波驱动信号。正弦波驱动信号驱动 LD 驱动芯片 iC-WJZ 工作，以使 iC-WJZ 输出正弦波驱动电流点亮 690nm 波长 LD 和 850nm 波长 LD。690nm 波长 LD 和 850nm 波长 LD 以与驱动正弦波电流相同的频率发出正弦波光，发出的光分别通过双尾纤光纤准直器的尾纤 1 和尾纤 2 传输到双尾纤光纤准直器前端的准直透镜焦点处，经过准直透镜扩束后，以近似平行光均匀入射被测生物组织。经过生物组织吸收和散射后的后向散射光子被放置在被测生物组织表面的芯径 1 ～ 3.5mm 塑料光纤接收。塑料光纤将接收的光子传输给探测器 APD 模块 C5460-01，探测器将接收到的光信号转换为电压信号，并对电压信号进行前置放大。电压信号直接被数据采集卡 PCI6259 采集传输给 PC 机。PC 机内部对采集到的信号进行数字锁定运算，提取光强变化信息，将光强变化信息转换为血液动力学参数变化，并进行存储和显示。

[0044] 图 3 所示为本发明实施案例之一基于 PC 机的便携式光纤近红外检测仪应用于在体前臂阻断实验结果图。实验过程中，将仪器探头绑在人体前臂，将血压计绷带绑在上臂，通过血压计对上臂加压，以实现对前臂血液供应的阻断导通控制。静息状态测量 30s，含氧血红蛋白 HbO_2，脱氧血红蛋白 Hb 和血容 Bv 没有变化，因此相对浓度变化为 0。然后加压至 200mmHg，阻断前臂血液的供给和回流。阻断后，前臂由于得不到血液供应，血液也无法回流，因此血容 Bv 基本保持稳定；肌肉组织需要不断消耗氧气，因此 HbO_2 减少，Hb 以同样的速率增加；当减压至正常状态时，淤积的静脉血得到快速释放，大量动脉血迅速涌入，都出现了“过偿”效应；随后 HbO_2，Hb 和 Bv 逐渐恢复至初始状态。该实验测量的前臂血管内的血液动力学参数的变化与实际的生理变化过程相符合，表明仪器可以对人体的血液动力学参数变化进行有效监测。

[0045] 最后所应说明的是，以上具体实施方式仅用以说明本发明的技术方案而非限制，

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尽管参照较佳实施例对本发明进行了详细说明，本领域的普通技术人员应当理解，可以对本发明的技术方案进行修改或者等同替换，而不脱离本发明技术方案的精神和范围，其均应涵盖在本发明的权利要求范围当中。

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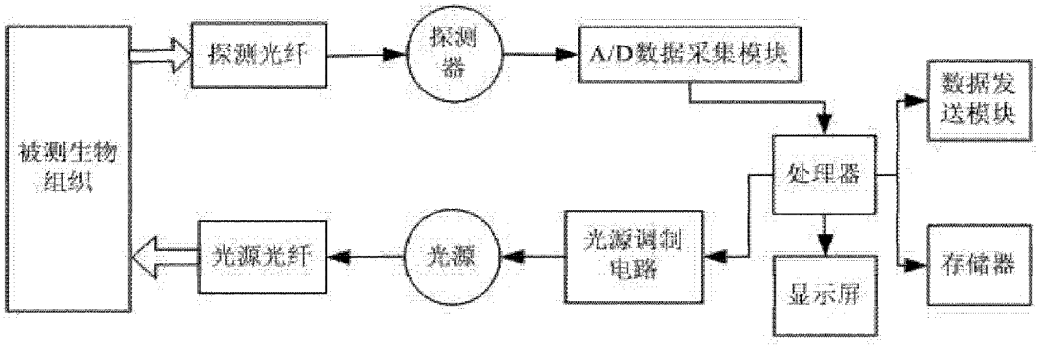


图 1

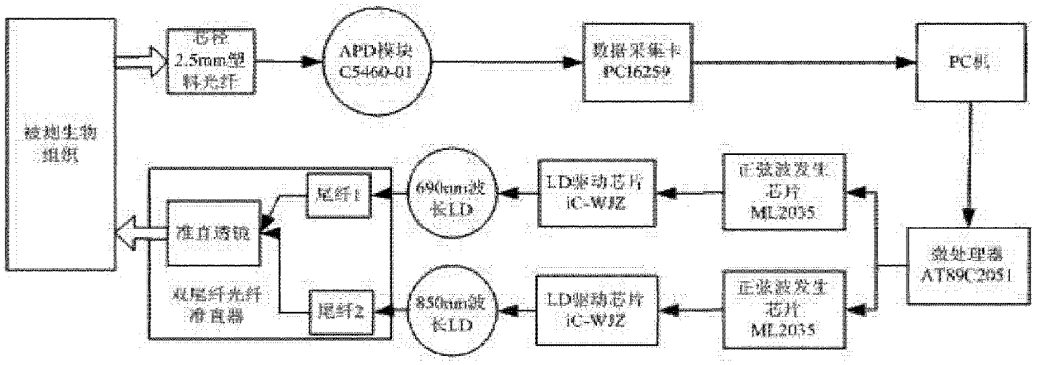


图 2

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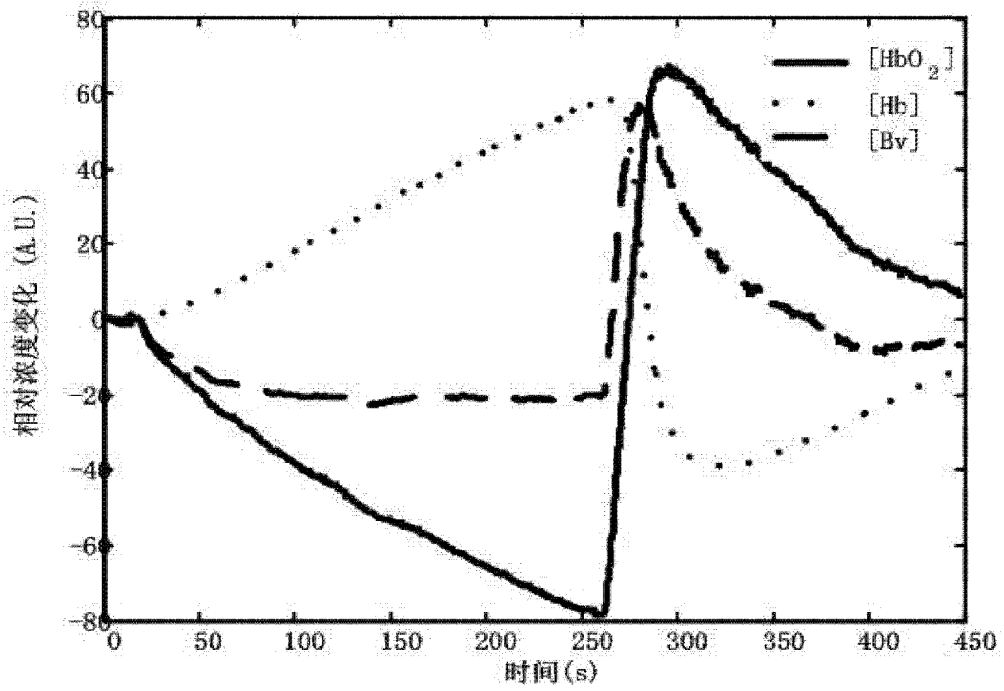


图 3

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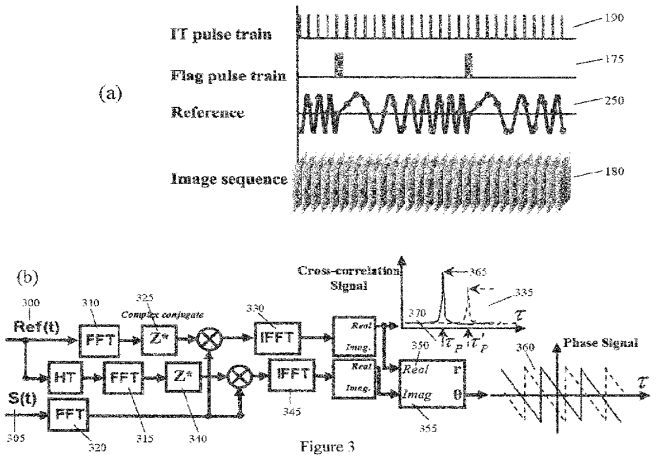


Figure 3

(57) **Abstract**: Systems and methods for improved thermophotonic imaging are provided in which both amplitude and phase image information is obtained with a high signal to noise ratio and depth-resolved capabilities. Image data obtained from an imaging camera is dynamically averaged and subsequently processed to extract amplitude and/or phase image data. The system may be configured for a wide range of imaging modalities, including single frequency modulation (thermophotonic lock-in imaging), Thermal-Wave Radar imaging or Thermophotonic Radar imaging involving chirp modulation, and Binary Phase Coded Modulation. Such imaging modalities may find application in many diverse areas, including non-destructive testing and biomedical diagnostic imaging including the imaging of teeth and monitoring changes in the tooth over time which are due to pathology such as dental caries or erosion.

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SYSTEMS AND METHODS FOR THERMOPHOTONIC DYNAMIC IMAGING

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Application No. 61/471,772, titled "SYSTEMS AND METHODS FOR THERMOPHOTONIC DYNAMIC IMAGING" and filed on April 5, 2011, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to systems and methods of non-destructive subsurface imaging. More particularly, this invention relates to systems and methods for thermophotonic imaging.

Thermographic and thermophotonic imaging methods have found widespread use in applications such as non-destructive testing of various materials and biomedical diagnostic imaging. While numerous methods have been developed and described in the literature, most solutions proposed to date have relied on methods involving single frequency analysis of amplitude and phase images. Such methods, while well suited for some specific applications, often fail in applications that demand higher sensitivity. Another disadvantage of known thermographic and thermophotonic imaging methods is the use of low speed imaging techniques, which can place significant limitations on depth and/or spatial resolution.

Accordingly, despite the existence of a number of thermographic and thermophotonic imaging modalities, there remains a need for imaging solutions that deliver higher sensitivity, lower detection limit, increased speed, and improved depth

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resolution. In industrial quality control, there is a need for fast and reliable monitoring of substrate integrity and process-induced defects during manufacturing and component reliability testing, for example in identifying subsurface cracks and delaminations in automotive and aerospace components and surface coatings, respectively. In oral health care, there is a need to have an imaging system that can image an entire tooth surface or group of teeth so as to provide the oral health care provider with the location of dental caries or defects in teeth and or dental materials.

As compared to conventional thermographic imaging, which monitors contrast due to thermal and/or mechanical property inhomogeneities of materials (thermographic contrast), thermophotonic imaging, in addition to thermographic contrast, involves amplified contrast due to optical property inhomogeneities. Both modalities are based on the generation and detection of (photo)thermal waves in a sample.

SUMMARY

Systems and methods for improved thermophotonic imaging are provided in which both amplitude and phase image information is obtained with a high signal to noise ratio and depth-resolved capabilities. Image data obtained from an imaging camera is dynamically averaged and subsequently processed to extract amplitude and/or phase image data. The system may be configured for a wide range of imaging modalities, including single frequency modulation (thermophotonic lock-in imaging), Thermal-Wave Radar imaging or Thermophotonic Radar imaging involving chirp modulation, and Binary Phase Coded Modulation. Such imaging modalities may find application in many diverse areas, including non-destructive testing and biomedical diagnostic imaging including the imaging of teeth and monitoring changes in the tooth

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over time which are due to pathology such as dental caries or erosion.

In a first aspect, there is provided a method of performing thermophotonic imaging, the method comprising the steps of: providing a sample; providing an optical source having a wavelength selected to generate photothermal radiation within the sample; providing an imaging camera with an optical bandwidth selected for detection of the photothermal radiation; generating a reference waveform comprising a plurality of modulation cycles; producing a modulated optical beam by modulating an intensity of an optical beam emitted by the optical source according to the reference waveform; illuminating the sample with the modulated optical beam;

imaging the photothermal radiation with the imaging camera; recording a plurality of dynamically averaged image frames at time offsets corresponding to different values of the reference waveform; and processing the dynamically averaged image frames and the reference waveform to obtain an image relating to the photothermal radiation.

The dynamically averaged image frames may be obtained according to the following steps: recording a plurality of image frames at times corresponding to different values of the reference waveform; repeating, one or more times, the step of recording the image frames at times corresponding to different values of the reference waveform, and dynamically averaging the recorded images for each the different value of the reference waveform, thereby obtaining dynamically averaged image frames.

The step of recording the plurality of image frames at different values of the reference waveform may comprise recording the plurality of image frames over a single modulation cycle/correlation period, and may be obtained over more than one modulation cycle, where a frame acquisition rate of the imaging camera may less than

a modulation frequency of the reference waveform.

The method may further comprise the step of recording, for each image frame of the plurality of image frames, a substantially instantaneous value of the reference waveform, and may further comprise generating a quadrature waveform based on the reference waveform, and recording, for each image frame of the plurality of image frames, a substantially instantaneous value of the quadrature waveform.

An integration pulse train may be generated comprising a series of pulses, wherein each pulse is generated at a time at which an image frame is acquired by the imaging camera, wherein the step of generating of the reference waveform is triggered according to the integration pulse train. The integration pulse train may be generated by the imaging camera.

A flag pulse train may be generated comprising a series of pulses, wherein each pulse is generated at a commencement of a given modulation cycle/correlation period, and identifying one or both of a beginning and an end of the given modulation cycle/correlation period according to the flag pulse train. A modulation frequency of the reference waveform may be greater than approximately 0.01 Hz.

The reference waveform may comprise a single frequency and wherein the image is obtained by lock-in processing, and the step of processing the dynamically averaged image frames and the reference waveform may comprise, for each pixel in the image frame, performing the steps of: multiplying the dynamically averaged image frames by the reference waveform to obtain in-phase product values; and summing the in-phase product values to obtain an in-phase sum; generating a quadrature waveform based on the reference waveform; multiplying the dynamically averaged image frames by the quadrature waveform to obtain phase-shifted product values; and summing the phase-shifted product values to obtain a phase-shifted sum.

The image may be an amplitude image, and wherein the processing further comprises calculating a magnitude of a complex quantity based on the in-phase sum and the phase-shifted sum. The image may be a phase image wherein the processing further comprises: calculating a phase angle of a complex quantity based on the in-phase sum and the phase-shifted sum.

The reference waveform may comprise multiple frequency components, and the reference waveform may comprise a frequency chirp and may be a binary phase coded waveform.

The image may be a cross-correlation peak amplitude image obtained by the steps of: obtaining a complex cross-correlation signal of the reference waveform and each pixel of the dynamically averaged image frames; and determining, for each the pixel, a peak amplitude value of a peak in a real part of the cross-correlation signal.

The image may be a cross-correlation peak delay image obtained by the steps of: obtaining a complex cross-correlation signal of the reference waveform and each pixel of the dynamically averaged image frames; and determining, for each the pixel, a delay of a peak in a real part of the complex cross-correlation signal.

The image may be a cross-correlation phase image obtained by the steps of: obtaining a first complex cross-correlation signal of the reference waveform and each pixel of the dynamically averaged image frames; obtaining a second complex cross-correlation signal of a quadrature waveform and each pixel of the dynamically averaged image frames, wherein the quadrature waveform is based on the reference waveform; forming a complex quantity comprising a real portion of first complex cross-correlation signal and a real portion of the second complex cross-correlation signal; and obtaining the phase image by determining, for each pixel, a phase angle of the complex quantity at a pre-selected time delay.

The sample may be selected from the group consisting of automotive components, aerospace components, an optical material, a laser material, a biomedical material, and a biological tissue.

The sample may be a material comprising one or more of a subsurface crack and a delamination. The sample may be an unsintered component in a green state.

The method may further comprise the step of determining a case hardness depth.

The sample may be a dental sample, tooth sample or whole groups of teeth. The method may further comprise the step of analyzing the image to determine one or more of a presence and a location of demineralization, erosion or dental caries in the dental or tooth sample. The method may further comprise the step of monitoring an evolution of one or more of demineralization, erosion and dental caries by comparing the image to one or more other images. The sample may be a dental or medical instrument and may be selected from the group consisting of endodontic instruments, catheters and other indwelling instruments.

The wavelength may be selected to lie within a range of approximately 600 nm to 2000 nm. The imaging camera may be selected to have a spectral response overlapping with at least a portion of the mid-infrared spectrum.

In another aspect, there is provided a system for performing thermophotonic imaging, the system comprising: an optical source having a wavelength selected to generate photothermal radiation within a sample; an imaging camera with an optical bandwidth selected for detection of the photothermal radiation, wherein the imaging camera is configured to acquire image frames a given frame rate and output an integration pulse train comprising a series of pulses, each pulse corresponding to a time at which an image frame is acquired by the imaging camera; a waveform

generating system for generating a reference waveform, wherein an output of the waveform generating system is connected to an input of the optical source for modulating an intensity of an optical beam emitted by the optical source; a processor programmed to dynamically average image frames obtained by the imaging camera, and to process the dynamically averaged image frames, the reference waveform and a quadrature waveform based on the reference waveform, to provide one or more of an amplitude image and a phase image; and a memory for storing dynamically averaged image frames.

A modulation frequency of the reference waveform may be greater than approximately 0.01 Hz. The imaging camera may comprise a frame acquisition rate that is less than a modulation frequency of the reference waveform. The wavelength may lie within approximately 600 nm to 2000 nm. A spectral response of the imaging camera may overlap at least a portion of the mid-infrared spectrum.

A further understanding of the functional and advantageous aspects of the disclosure can be realized by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments will now be described, by way of example only, with reference to the drawings, in which:

Figure 1 shows of a system that may be employed for thermophotonic imaging.

Figure 2 illustrates a method of thermophotonic lock-in imaging.

Figure 3 illustrates thermal-wave radar imaging, where (a) shows the waveforms and frames captured, and (b) provides a flow chart illustrating the method.

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Figure 4 (a) illustrates a method of binary phase code imaging. Theoretical simulation of CC signals using frequency (dashed) and phase (solid) modulation for absorbers at depths (b) 50 μm and (c) 1 mm below the surface using thermal and optical properties of dental enamel. Chirp: 0.1-4.9 Hz, 6.4 s; BPC: 2.5 Hz, 16 bit, 6.4 s.

Figure 5 shows (a) an optical image, (b) front (F) and side (S) dental radiographs of sample A1(human bicuspid tooth) before treatment; and (c) front (F) and side (S) dental radiographs (d) optical image of sample A1 after 10 days of demineralization treatment with an artificial caries solution within the treatment window; thermophotonic lock-in phase images of sample A1 (e) before treatment and after (f) 2, (g) 4, (h) 8, and (i) 10 days of demineralization with an artificial caries solution within the treatment window; (j) phase profiles along the dashed line shown in figure 5i for samples at several demineralization stages (dashed vertical lines show the location of the treatment window); and (k) Transverse micro-radiographic mineral profile along the center of the treatment window of the 10-day demineralized sample.

Figure 6 shows (a) an optical image of sample A2, the occlusal surface of a maxillary molar with stained pits and fissures; thermophotonic (b) amplitude and (c) phase images of sample A2 obtained at 10 Hz; thermophotonic (d) amplitude and (e) phase images of sample A2 obtained at 100 Hz; and (f)-(i) transverse micro-radiographic mineral profiles of points f-i, respectively, as indicated in (e).

Figure 7 provides images of (a) sample B1, (left) the plastic step wedge (right) inside the scattering medium, (b) sample B2, strip pattern left to right: green, transparent, black, and (c) sample B3, where the squares in (c) indicate the locations of two demineralization (artificial caries) treatment windows.

Figure 8 plots thermal wave radar and phase lock-in (LI) imaging of sample

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B2 , with LI thermography phase images at (a) 0.01Hz and (b) 1Hz; (c) Cross-correlation (CC) amplitude image (chirp frequency bandwidth: 0.01-1 Hz in 6s); (d) mean horizontal LI phase profile of figure (a); and distribution of (e) LI phase and (f) CC amplitude values over the steps.

Figure 9 plots thermal wave radar imaging of sample B2 using (a) CC amplitude, (b) CC peak delay time, (c) CC phase and their mean horizontal profiles (d), (e), and (f), respectively (chirp frequency bandwidth: 0.01-1 Hz in 6s).

Figure 10 plots thermal wave radar and thermophotonic lock-in imaging of sample B3, showing (a) CC amplitude image, (b) CC peak delay time image, (c) CC phase image (chirp frequency bandwidth: 0.01-1 Hz in 6s); thermophotonic lock-in phase images at (d) 0.01 Hz and (e) 1 Hz; and (f) transverse micro-radiographic mineral profiles at points 1-3 indicated in figure (c)

Figure 11 plots (a) binary phase code and (b) phase LI imaging of sample B1, and distribution of (c) binary phase code image and (d) phase LI image values over the steps of sample B2.

Figure 12 provides thermophotonic lock-in and binary phase code images of sample B3, with thermophotonic lock-in (a) amplitude and (b) phase images 1 Hz; and binary phase code (c) amplitude image (d) peak delay time image and (e) phase image.

Figure 13 (a) Exploded view of the cross-shaped sample simulating two absorbers at different depths. Conventional LIT (b) Amplitude and (c) phase image. binary phase code peak delay time image matched to the camera temporal data of (d) point 1 and (e) point 2, as indicated in part (b), using a 3-bit [1 1 -1] code.

Figure 14 (a) Teeth matrix with hidden inter-proximal early caries. The rectangle shows the imaged area. (b) Conventional LIT and (c) binary phase code

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phase images of teeth matrix. (d-f) thermal coherence tomographic images obtained as several delay times differentiating between the defective (e) and healthy (f) regions.

Figure 15 (a) Optical image of goat bone. The rectangle shows the images area. (b) binary phase code phase images at 1 Hz using a 7 bit binary code.

Figure 16 illustrates the method of asynchronous undersampling for lower frame acquisition rate imaging cameras.

DETAILED DESCRIPTION

Various embodiments and aspects of the disclosure will be described with reference to details discussed below. The following description and drawings are illustrative of the disclosure and are not to be construed as limiting the disclosure. Numerous specific details are described to provide a thorough understanding of various embodiments of the present disclosure. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of embodiments of the present disclosure. It should be understood that the order of the steps of the methods disclosed herein is immaterial so long as the methods remain operable. Moreover, two or more steps may be conducted simultaneously or in a different order than recited herein unless otherwise specified.

As used herein, the terms, "comprises" and "comprising" are to be construed as being inclusive and open ended, and not exclusive. Specifically, when used in the specification and claims, the terms, "comprises" and "comprising" and variations thereof mean the specified features, steps or components are included. These terms are not to be interpreted to exclude the presence of other features, steps or components.

As used herein, the term "exemplary" means "serving as an example, instance,

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or illustration," and should not be construed as preferred or advantageous over other configurations disclosed herein.

As used herein, the terms "about" and "approximately", when used in conjunction with ranges of dimensions of particles, compositions of mixtures or other physical properties or characteristics, are meant to cover slight variations that may exist in the upper and lower limits of the ranges of dimensions so as to not exclude embodiments where on average most of the dimensions are satisfied but where statistically dimensions may exist outside this region. It is not the intention to exclude embodiments such as these from the present disclosure.

As used herein, the term "thermophotonic imaging" relates to the generation of images based on thermal infrared photons emitted from surface and subsurface regions of opaque or non-opaque matter, resulting from photothermal excitation of a sample with a light source such as a laser. The emitted infrared photons carry optical absorption information at the excitation wavelength as well as at the detection spectral band determined by the spectral response of the infrared imaging detector. The case of optically opaque samples, conventionally known as "infrared thermographic imaging", which involves only thermal properties, is understood to be incorporated by implication in the opaque limit of thermophotonic imaging. As compared to conventional thermographic imaging which monitors contrast due to thermal and/or mechanical property inhomogeneities of materials (thermographic contrast), thermophotonic imaging, in addition to thermographic contrast, involves amplified contrast due to optical property inhomogeneities. Both modalities are based on the generation and detection of (photo)thermal waves in a sample.

Embodiments described below provide systems and methods for improved thermophotonic imaging. In a first embodiment, a system and method is provided in

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which photothermal image data are dynamically averaged and subsequently processed to determine both amplitude and phase image information with high signal to noise ratio. The system may be configured for a wide range of imaging modalities, including, but not limited to, single frequency modulation (thermophotonic lock-in imaging or thermophotonic lock-in imaging), chirp modulation (thermal-wave radar imaging or thermal wave radar imaging), and binary phase coded modulation (Binary Phase Coding imaging or binary phase code imaging).

Figure 1 shows a schematic of a thermophotonic imaging system 100 that may be utilized for a number of different imaging modalities. System 100 includes imaging camera 110 for detecting and imaging thermophotonic radiation, laser 120 for exciting a photothermal response in a sample 130, data acquisition system 140, and computing system 150 that is interfaced to camera 110 and/or data acquisition system 140 (in the example embodiment shown in Figure 1, computing system 150 is directly interfaced to camera 110 for reading both image data and data acquisition header data in image frames, as described further below). Sample 130 may be positioned using a sample positioning device, such as a 3-axis (XYZ) sample positioning system (not shown).

Laser 120 is modulated to produce a modulated optical beam that is directed onto the surface of an extracted sample tooth 130, which in turn leads to the generation of photothermal radiation from sample 130 that is subsequently detected by imaging camera 110. In order to obtain high signal-to-noise ratio (SNR) via phase-sensitive detection, a synchronous driving and data acquisition approach is employed, in which frames outputted by imaging camera 110 are synchronized with the modulation of laser 110 for further processing.

Referring now to Figure 2, system 100 is further described in the context of a

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thermophotonic imaging modality involving thermophotonic lock-in detection, which represents an illustrative yet non-limiting embodiment of an imaging modality compatible with system 100. Data acquisition system 140 generates analog in-phase reference waveform 160 and analog quadrature reference waveform 165, where quadrature waveform 165 is phase shifted by 90° relative to in-phase waveform 160. Alternatively, the quadrature reference waveform may be computed from the Hilbert Transform of the in-phase reference signal.

In-phase waveform 160 is provided to the modulation input 170 of laser system 120, (shown in Figure 1). In response to in-phase waveform 160, the intensity of the emitted laser light is modulated, where the modulation profile of the laser intensity follows that of in-phase waveform 160 plus a DC offset.

Imaging camera 110 obtains image frames at a defined frequency as shown by integration pulse train (IT pulse train) 190 in Figure 2. Integration pulse train 190 is provided (e.g. as a TTL pulse train) from imaging camera 110 to data acquisition system 140 to trigger the generation of in-phase waveform 160 and quadrature waveform 165 by data acquisition system 140. Integration pulse train 190 also triggers the generation of flag pulse train 175 by data acquisition system 140, where flag pulse train 175 provides a "high" pulse at the beginning of each modulation cycle, as shown in Figure 2.

In the embodiment shown in Figure 1, imaging camera 110 is capable of providing a header for each recorded image frame, where the header includes the measurement of two values that are measured at a time that is substantially instantaneous with the detection of an image frame. The two values are obtained from two analog signals corresponding to instantaneous values of waveforms 160 and 165. Data acquisition system 140 provides these waveforms to imaging camera 110 for

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inclusion of the two values in the frame header, thereby providing a measurement of their values at a time that is substantially simultaneous to the instant that the frame is captured. Values from flag pulse train 175 are also stored in the frame header to allow for the determination of the beginning of each waveform period, which is used for averaging purposes as further described below. It is to be understood that the direct interfacing of computing system 150 to camera 110, as shown in Figure 1, is but one of many different possible system implementations. In other embodiments, computing system may be interfaced to camera 110 and/or data acquisition system 140 for synchronous acquisition of both image and modulation waveform instantaneous data, as further described below.

During image acquisition, computing system 150 reads image frames from imaging camera 110 via image sequence 180, and queries the frame headers until it finds a frame whose flag pulse train is "high" (the beginning of a modulation cycle). After a "high" pulse is detected, computing system 150 reads a sequence of frames that correspond to one complete modulation cycle, where the number of frames and delay between frame acquisition events is determined based on the frame rate of imaging camera 110 and the modulation frequency of the in-phase waveform 160. The frames are stored in a buffer (e.g. a 3D buffer) in a memory (such as computer RAM). By performing these steps, system 100 obtains a series of individual imaging frames corresponding to one modulation cycle.

To obtain an improved SNR of the acquired image frames, the above steps are repeated and the values for each frame of one complete modulation cycle are averaged in the buffer to reduce the stochastic noise. Most averaging algorithms read the signal corresponding to all recorded cycles and then initiate the averaging processes. Unfortunately, due to the huge flow of data needed to meet the bandwidth

demands of the image frames, such an averaging methodology fails at high frame rates, such as those that are preferably used in the present embodiment.

Accordingly, in a one embodiment, the image frames are dynamically averaged, where the frames corresponding to one modulation cycle are collected and dynamically processed to determine a running average. Initially, a first set of image frames corresponding to a first modulation cycle are collected and stored in a memory location. Subsequently, image frames are obtained for a second modulation cycle, and the recorded image frame values are dynamically averaged. This process is repeated for subsequent modulation cycles, with the averaging based on the number of modulation cycles that have been processed, with the result that an averaged set of image frames with improved SNR is obtained. This provides a dramatic improvement in memory management and speed, and requires significantly less sophisticated computer hardware.

After having obtained an averaged set of image frames over a modulation cycle, the averaged frame sequence, shown at 180 as f(t) in Figure 2, corresponding to averaged image frames, is processed to obtain amplitude and phase images. This is performed by weighting each pixel in the image for each frame obtained, where the pixel value is weighted once by the in-phase reference signal 160 and once by the quadrature reference signal 165 in two separate channels. The weighted sequences are then separately summed to get the S^0 and S^{90} images, as shown in steps 200 and 210 of Figure 2, respectively. Finally, using equation 1 for each pixel the amplitude and phase images are calculated:

$$A = \sqrt{\left(S^0\right)^2 + \left(S^{90}\right)^2} \quad \text{and} \quad \Phi = \arctan\left(S^{90}/S^0\right) \quad (1)$$

Computing system 150 may be programmed with a signal acquisition and/or processing program for processing the data received from imaging camera 110 and/or

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data acquisition device 140, and for performing the aforementioned averaging steps and calculation of the amplitude and phase images. For example, generic data processing programs may be provided commercially or created for specific applications associated with the thermophotonic imaging modalities disclosed herein. A suitable programming medium for the creation of such a program is the LabView environment. This environment provides a flexible platform for adapting the imaging software to non-destructive / diagnostic groups of equipment (set-ups) for application specific to particular materials and configurations (e.g. engineering materials NDT, biomaterials diagnostics, dental caries imaging).

Unlike lock-in thermography, which is mostly used in non-destructive testing of metals and other opaque structural materials at very low modulation frequencies (on the order of 0.01Hz or so), and in which low camera frame rates (usually 20 fps), and high optical excitation power (high SNR signal) are used without averaging, in thermophotonic imaging of biological samples and industrial materials with defects very close to surface, one may need high frequency thermal waves and low optical excitation power (poor SNR signal) to meet safety criteria. Therefore, in such cases, it can be advantageous to employ very high camera frame rates and a real-time averaging methodology, as provided, according to the present embodiment.

While the above embodiments provide exemplary systems and methods for obtaining thermophotonic images, it is to be understood that the systems and methods may be varied without departing from the spirit and scope of the aforementioned embodiments. For example, referring now to Figure 1, although system 100 is shown as comprising computing system 150 and data acquisition system 140, these elements of the apparatus may be provided in a number of different formats. Computing system 150, which comprises a processor and a memory, may be directly integrated with data

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acquisition system 140. For example, data acquisition system 140 may reside in total or in part on a hardware card housed within an apparatus that also comprises a processor and a memory.

Laser system 120 may further comprise additional sub-components or subsystems such as, but not limited to, a laser diode emitter, laser driver, fiber coupled output, collimator, and thermoelectric cooler and controller. In one exemplary embodiment, laser system 120 has two laser diodes so as to provide improved optical contrast of a type of sample through large differential absorption (for example, 808 nm and 1120 nm). Typically, laser diodes are mounted on thermoelectric coolers and the diode assembly is fixed on an air cooled heat sink through a heat conductive thermal pad. The laser light may be delivered to the sample through an optical fiber and a collimator. A collimator and/or spatial filter may be provided to maintain a relatively uniform optical intensity on the interrogated surface. The thermoelectric controller provides the cooling power to the thermoelectric coolers and controls the temperature of the laser diode. The laser driver may be employed to provide the electrical power needed to operate the laser diode and can modulate the laser light intensity according to the analog modulation signal it receives at its "mod in" terminal.

Furthermore, it is to be understood that optical source need not be a coherent light source such as a laser, but may instead be an incoherent source such as a LED, provided that sufficient optical intensity is achieved to obtain a measurable thermophotonic image signal. With the advent of high-power LEDs, one may employ a high-power infrared LED or LED array in place of a laser source. LED arrays are significantly less expensive than laser sources and generally do not require complicated cooling systems. This strategy can be used because in the proposed

methodologies it is the thermal (conductive and radiative) response from the sample that is investigated, and not the purely optical response.

As noted in the example embodiment provided above, data acquisition system 140 is capable of generating and/or providing waveforms 160 and 165 in response to the integration pulse train 175 generated by the imaging camera. In a non-limiting example, data acquisition system may be a DAQ board such as National Instrument Multi Data acquisition device (NI USB-6229 BNC), and the like, which may be directly integrated with or housed within computing system 150. Such a multifunction data acquisition (multiDAQ) system can generate and acquire analog signals simultaneously and has two independent counters and 48 digital I/O channels for synchronization applications. The data acquisition system may be connected to the computer with a USB port and may be configured to communicate with other devices through BNC connections.

Computing system 150 may be interfaced to imaging camera 110 through an interfacing device such as a networking card. For example, the GigE network PCI card may be employed to provide a suitable interface between the camera and the computer for rapidly transferring image frames to the memory of the computing system 150 according to the GigE standard.

As noted above, the sample 130 and/or laser source may be positionable relative to one another. For example, a sample positioning system may be provided that consists of one or more single axis translation stages mounted to move the sample relative to the incident laser beam in X, and optionally Y and Z directions. A rotational stage may be added to this assembly to assist in the placement of the sample in the focal plane of the camera.

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While system 100 as disclosed above is capable of averaging numerous modulation cycles of the signals before processing them, it is also possible to perform that averaging based on the computed amplitude and phase images as opposed to the image frames.

Such an embodiment may be achieved by reading, at a given point in time, a sequence of frames corresponding to one or more modulation cycles, processing the image frames as outlined above, and calculating the desired diagnostic images (i.e. amplitude, phase) and then repeating these steps and averaging the amplitude and phase images. While this "processing, then averaging" mode is less effective in eliminating the stochastic noise than the "averaging, then processing" strategy, it requires less sophisticated triggering/synchronization equipment. For example, this embodiment involves the simplification of the control section of the camera and signal processing system with respect to triggering. This approach will yield non-triggered, yet synchronized, data arrays resulting in an image of somewhat compromised quality.

Furthermore, although system 100 is shown in Figure 1 in which the waveforms 160, 165 and 175 are provided by data acquisition system 140 to imaging camera 110 for incorporation of the substantially instantaneously measured values into the frame header, it is to be understood that the values may be provided according to alternative system implementations. Such embodiments may be useful in cases where imaging camera 110 is not equipped or configured for the incorporation of a header in each image frame. For example, in one non-limiting embodiment, the waveforms 160, 165 and 175 may be directly provided to computing system 150 by data acquisition system 140, optionally along with integration pulse train 190 from imaging camera 110 for triggering. Provided that the relative time delay between the

reception of the waveforms and the generation and/or reception of image frames may be determined (for example, by measuring a delay between system components), the appropriate values of the waveforms corresponding to the measurement of image frames may be determined.

Alternatively, the waveforms 160, 165 and 175 may be generated directly by computing system 150 (optionally triggered by integration pulse train 190 provided by imaging camera 110), and the correlation between the appropriate values of the waveforms and the acquisition of image frames may be determined based on a known system delay. These embodiments may be applied to the system shown in Figure 1, or in the system described above in which the synchronization of triggering is not necessary.

In one embodiment, imaging camera 110 is an infrared imaging camera that is sensitive in the infrared spectrum. Imaging camera 110 may incorporate the necessary optical components for the collection and detection of photothermal radiation, or one or more of the optical components may be externally mounted or otherwise provided. For example, imaging camera may include an extension tube supporting an objective lens.

In one exemplary embodiment, imaging camera 110 is a focal plane array (FPA) mid-infrared camera. A suitable but non-limiting example of such a camera is the Cedip Titanium 520M (France), which has a spectral range of 3.6 – 5.1 μm and maximum frame rate of 175 Hz at full frame. The camera's detector array consists of 320x256 Indium Antimonide (InSb) elements with element size of 30x30 μm^2. An extension tube and a objective lens (such as Cedip MW50 L0106, a 50-mm-focal-length lens) may be employed to obtain a magnification of (for example, of unity) relative to the interrogated surface of sample 130.

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While the mid-infrared camera may be preferred for obtaining optimum results for some sample types, one may also employ less expensive near- or far-infrared cameras, generally with the performance trade-off of a reduced signal-to-noise ratio. However, the low signal to noise ratio can be mitigated, at least in part, by a number of methods such as, for example, increasing the number of averages, using matched filtering signal processing methods (thermal wave radar and binary phase code) described above, increasing the optical source intensity, increasing the camera integration time, and/or improving the optical collection efficiency. It is expected to be more effective to employ a far infrared camera to capture thermal infrared photons due to the peak of the blackbody radiation being located in that spectral range, although the spectral transmissivity of the interrogated material must also be considered in determining the thermal infrared photon emission flux to the camera following self-absorption.

Furthermore, in selected embodiments, uncooled imaging cameras may be employed to simplify the system and/or reduce cost. The cooling system of a camera is one of the factors that make the camera expensive. Uncooled cameras are significantly less expensive but at the same time less sensitive. This problem can be solved by increasing compensation for a reduced performance by using one of the mitigating methods described above.

In another embodiment, a camera with a lower frame acquisition rate may be employed. While lowering the frame rate does not significantly affect the performance of thermophotonic lock-in imaging, the sampling period can be critical in matched filtering methodologies (thermal wave radar and binary phase code) as it determines the depth resolution. Two strategies can be followed to overcome the depth resolution limitation while using a low-grade (low frame rate) camera.

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In a first method, synchronous/asynchronous undersampling may be employed, whereby the frame rate is chosen such that the data are captured from many modulation cycles instead of just one. This embodiment is illustrated in Figure 16. Although this sampling strategy increases the total sampling duration, this alternative implementation enables the use of a lower-grade camera to access image depth resolution commensurate with that of the foregoing high-grade camera. The combination of critical undersampling determination with the desired thermal-wave depth penetration, and their software implementation thus provide a unique and important benefit to system performance.

The undersampling frequency (f_s) can be determined as follows:

$$f_s = f_{\text{lock-in}} \; / \; [m+(1/n)] \qquad (1a)$$

where f_s is the undersampling frequency, $f_{\text{lock-in}}$ is the desired lock-in frequency (or alternatively, chirp/binary phase code repetition rate), m is an integer number and is called the order of undersampling, and n is the number of frames per correlation period. In Figure 13, m=1 and n=12, that is one frame is captured in every m=1 modulation cycle and at the end of the process the sampled modulation cycle (i.e. correlation period) consists of n=12 frames[8].

In a second method, artificial oversampling is performed as per the sampling theorem, which states that if the Fourier transform of a function *h(t)* is zero for all frequencies above a certain frequency f_c, then the continuous function *h(t)* can be uniquely determined from a knowledge of the sampled values. So, if the function is sampled at T= 1/2 f_c, then one can use the expression below to reconstruct the waveform at any sampling/frame rate:

$$h(t) = T \sum_{n=-\infty}^{\infty} h(nT) \frac{\sin(2\pi f_c (t-nT))}{\pi (t-nT)} \qquad (2)$$

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The methodology is also known as "Sinc interpolation". Therefore, one can use a low frame rate camera and then use Sinc interpolation to improve the sampling resolution. The determination of cut off frequency, f_c, satisfying the requirement of a predetermined thermal diffusion length (depth resolution) may be performed according to equation 5, as further described below.

An alternative option for an infrared camera for use with system 100 may be provided by modifying a digital visible spectrum camera such as a commercial digital camera or a webcam. Such cameras may be modified to be sensitive in the near-infrared spectral region by removing the infrared filter and then inserting an infrared band pass filter in the optical path of the detector array. The performance degradation that is likely based on use of such a camera may be mitigated, at least in part, by the methods listed above.

An alternative option for an infrared camera for use with system 100 may be provided by modifying a digital visible spectrum camera as noted above and using methods listed above to handle performance degradation. The output from this camera would be in color with color linked to the status of the specimen under examination. In another embodiment, the camera may be a monochrome camera, and the defect region may be displayed in a unique false colour. The defect may be identified automatically by image processing (for example, using known methods to identify regions of an image based on intensity and/or the presence of a border feature). Alternatively, the defect may be identified in response to input from a user or operator viewing the image.

In one example embodiment, the defect size may be correlated with its displayed colour. For example, an area where there is a large defect may be displayed (and optionally imaged) in red while an area which is sound or healthy may be

displayed (and optionally imaged) in green. An area where the defect is small can be displayed (and optionally imaged) in yellow. This gradation from green to yellow to red would help the operator visually understand the relative size of the defect, and in the case of dental imaging, would assist in visually assessing the severity of any detected defects.

Another imaging modality that is suitable with system 100 employs thermal-wave radar imaging. In thermal wave radar imaging chirp modulation is used instead of the aforementioned method of single frequency modulation (thermophotonic lock-in) modality and the matched filtering signal processing method is employed to increase the SNR. For non-opaque targets, this method is referred to "thermophotonic radar imaging". It should be noted that this methodology is completely different from thermophotonic lock-in imaging and is a depth selective method as opposed to a depth integrated method in thermophotonic lock-in imaging. As a result, thermal wave radar not only probes deeper into a sample, but also provides improved resolution of details and faster image acquisition due to its high SNR (i.e. requires less averaging).

Figure 3(a) explains the thermal wave radar imaging method graphically. As in the thermophotonic lock-in method, a sequence of image frames are acquired in combination with the values indicating the values of the waveforms 160, 165 and 175. The role of the flag pulse train 175, the integration pulse train 190, and the averaging method, are the same as in the thermophotonic lock-in method described above. However, unlike the case of thermophotonic lock-in in which one modulation cycle is being averaged, it is one chirp cycle of the chirped reference signal 250 that is averaged in the thermal wave radar imaging or the thermophotonic radar imaging method.

Figure 3(b) depicts the signal processing block diagram of thermal wave radar

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imaging according to the cross-correlation (CC) theory (matched filtering theory):

$$CC(\tau)=\varepsilon\times\Im^{-1}\left\{REF(\omega)^{*}\ S(\omega)\right\} \qquad (3)$$

where REF(ω) 300 and S(ω) are the Fourier transforms of the reference/modulation signal (Ref(t)) and the highly noised photothermal signal (s(t)), ε is the emissivity and $\Im^{-1}$ and * denote the inverse Fourier transform and complex conjugate operators, respectively. In matched filtering, the role of chirped modulation is to compress the energy delivered by the chirp into a narrow correlation peak which enables imaging with high axial resolution. The result is a reduction in the width of the CC main lobe (peak) and an increase in the amplitude of the peak as the area below it needs to be conserved. In the case of a linear frequency sweep, the signal-to-noise ratio (SNR) gain factor of the ideal matched filter is equal to the time-bandwidth product of the chirp. Theoretical and experimental studies have shown that this increase in SNR also holds in the photothermal fields.

While the amplitude of the CC peak relies strongly on the amplitude of the received signal, its location in the delay time axis (τ_p) is linked to the depth of the signal source. One can further develop this concept by calculating the CC phase (schematically in figure 3(b)) and find:

$$\theta_{CC}=\frac{\varepsilon\times\Im^{-1}\left\{REF(\omega)^{*}\ S(\omega)\right\}}{\varepsilon\times\Im^{-1}\left\{\left[-i\,\mathrm{sgn}(\omega)\,REF(\omega)\right]^{*}\ S(\omega)\right\}} \qquad (4)$$

where sgn(ω) and i are the signum function and standard imaginary unit, respectively. The expression inside the squared bracket is the Fourier transform of the quadrature reference signal. The significance of CC phase is that according to equation 4 the emissivity is cancelled out and as a result the CC phase is an emissivity-normalized quantity.

In light of the above, after the averaging step, the temporal signal from each

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pixel is processed according to figure 3(b). Initially, the Fourier transform of reference *Ref(t)* 300, quadrature signal (i.e. Hilbert transformed reference signal), and averaged photothermal signal *S(t)* 305 are obtained at 310, 315 and 320, respectively. The complex conjugate 325 of the reference spectrum is then multiplied by the spectrum of the photothermal signal which is proportional to the emissivity, and the inverse Fourier transform is obtained at 330, the real part of which generates cross-correlation signal 335. Similarly, the complex conjugate 340 of the Hilbert transform of the reference spectrum is multiplied by the spectrum of the photothermal signal which is also proportional to the emissivity, and the inverse Fourier transform is obtained at 345. The phase signal 360 is then provided by taking, as its real part, the real part 350 of the inverse transform 330, and as its imaginary part, the real part 355 of inverse transform 345.

From these calculated signals, contrast parameters may be generated and displayed as images. The following are a non-limiting list of parameters that may be provided for generating images:

(a) the *cross-correlation amplitude image*, in which the contrast parameter is the amplitude of the cross-correlation peak;

(b) the *cross-correlation peak delay time image*, in which the contrast parameter is the location of the cross-correlation peak in the delay time axis (τ_p); and

(c) the *emissivity normalized cross-correlation phase image*, in which the contrast parameter is the phase value at zero delay time calculated from equation 4.

In one example embodiment, one or more of these images, namely the cross-correlation amplitude image, the cross-correlation peak delay time image, and/or the

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emissivity normalized cross-correlation phase image, are generated and employed to infer information about the sample 130.

The above images are to be contrasted with known methods of processing thermophotonic image data. In the Radar sciences, matched filtering has been used since the early 1940s to detect pre-known (deterministic) signals within highly noised channels and to augment the range resolution. In 1986 Mandelis et al. in a series of papers introduced this method to the photothermal field through the mirage (photothermal beam deflection) effect[4(a-c)]. Recently, Mulaveesala et al.[5] and Tabatabaei and Mandelis[6] (Thermal-Wave Radar) have applied this methodology to imaging in the photothermal field. For example, in the method of Mulaveesala et al.[5](which is based on a pulse compression technique), a completely different approach is taken to calculate a so-called "phase image" from a chirped reference signal. Instead of processing the phase image according to all components in the frequency domain as in equation 4, the method of Mulaveesala et al. is based on demodulating the camera signal at a specific frequency. This method is completely different from the inventive methods disclosed herein and has long been used in the field of Pulse Phase Thermography[9]. More specifically, the phase image of Mulaveesala et al. is obtained by computing the Fourier transform of a pixel signal, and the value of this Fourier transform at the desired frequency will be a complex number. The phase is obtained by calculating, based on this complex frequency, the phase value tan^{-1}(imaginary part/real part). In fact, those skilled in the art will appreciate that this approach of phase calculation was first introduced in Pulse Phase Thermography[9] . This phase value is the phase of a single frequency thermal-wave; it is not a true matched filtering/cross-correlation calculation.

In contrast, according to the methodology disclosed herein, which is shown in

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the block diagram of Figure 3, the complex conjugate phase is calculated using *all the frequency components of the chirp through cross-correlation/matched filtering* of reference and quadrature signals. In summary, the phase images that are obtained according to the methods of Mulaveesala et al. result in depth integrated images over a thermal diffusion length controlled by the modulation frequency, in contrast to the method disclosed herein which results in depth-resolved (or depth-selective) imaging. The method disclosed herein is the result of correlation processing, otherwise known as "matched filter compression". As will be seen in the single frequency image of Figs 10d and 10e, compared to the matched filter compression generated images of Figs. 10b and 10c, this difference in approach has huge contrast enhancement implications in favor of matched filter compression.

Furthermore, unlike known imaging modalities such as those disclosed by Mulaveesala et al. , the present embodiments utilize thermophotonic imaging, which is applicable to a wide range of imaging applications beyond opaque sample imaging applications (such as imaging of metals). In particular, and as further described below, the optical scattering and absorption properties of dental and other biomaterials introduce a non-extrapolatable factor in imaging, which cannot be readily perceived by one skilled in the thermographic imaging, as frequency ranges, wavelengths, delay times etc. are all very different and image contrast optimization is controlled by the diffusion-wave centroid determined by the thermal diffusion length and optical absorption depth (or extinction depth, in case of turbid media) according to equation 5(b) as shown below.

Embodiments provided herein also improve over known imaging modalities that employ very low frequencies, such as those typical of thermography. Such methods that rely on low frequencies may be applicable for deep subsurface metal

defects, but are insufficient for thermal-wave radar in materials such as teeth and surface coatings, where high frequencies are needed for critical spatial and temporal (axial) resolution. In contrast to such low-frequency applications, the present embodiments may be employed for frequencies up to several hundred Hz via the aforementioned signal processing and data handling methods. Moreover, the embodiments disclosed herein may be adapted for use with inexpensive slower IR cameras in place of more expensive IR imaging cameras. Accordingly, the embodiments provided herein are especially adapted for thermophotonic imaging of non-opaque solids, but are also valid in the limit of opaque targets upon appropriate parameter adjustment.

The aforementioned embodiment, in which chirp modulation is employed in thermal wave radar imaging and thermophotonic radar imaging, provides a reduction in the width of the cross-correlation peak. This not only improves the depth resolution and allows for depth-selective imaging, but also increases the height of the peak (i.e. SNR) as the area below it needs to be conserved.

In another embodiment, an alternative approach is employed in which binary phase coding is utilized instead of a chirp to obtain an improved SNR. Binary phase coding is an alternative method that uses single frequency modulation but inverts some of the modulation cycles in a prescribed manner in order to achieve this goal. The signal processing method is the same as the aforementioned thermal wave radar imaging and thermophotonic radar imaging embodiment, and uses matched and mismatched filtering to detect a signal source. However, in the case of binary phase code imaging, the modulation waveform is a binary phase coded single frequency waveform. As a result, binary phase code imaging is considered as a narrow-band detection compared to thermal wave radar imaging/thermophotonic radar imaging and

experiences lower background noise level.

Figure 4 illustrates this method graphically for a 3-bit coded signal 260 ([1, 1, -1]) shown at reference waveform 400. The third cycle is inverted with respect to the other cycles to generate the binary phase code waveform, forming a single frequency signal that is coded according to the 3-bit sequence in Table 1.

Table 1. Binary phase code sequences[10].

length N	sequence c_k	filter coefficients w_k	relative efficiency
3	1 1 −1	1 1 0	66.67 percent
4	1 1 1 −1	1 1 1 −1	100.00 percent
5	1 1 1 1 −1	1 1 1 1 −2	90.00 percent
6	1 1 1 1 1 −1	1 1 1 1 1 −3	76.19 percent
7	1 1 1 1 1 1 −1	1 1 1 1 1 1 −4	64.93 percent
8	1 1 1 1 −1 −1 1 −1	1 1 3 1 −1 −1 3 −1	75.00 percent
9	1 1 1 1 1 −1 1 1 −1	1 1 6 1 1 −4 1 1 −4	60.11 percent
10	1 1 1 1 1 −1 1 −1 −1 −1	9 19 1 7 5 −9 25 −1 −7 −5	59.66 percent
11	1 1 1 1 1 −1 1 1 −1 −1 −1	71 20 47 17 80 −79 68 53 −49 5 −55	77.47 percent
12	1 1 1 1 1 −1 −1 1 1 −1 1 −1	2 1 1 2 1 −1 −2 1 1 −2 1 −1	88.92 percent
13	1 1 1 1 1 −1 −1 1 1 −1 1 −1 1	2 2 2 2 2 −3 −3 2 2 −3 2 −3 2	96.15 percent
14	1 1 1 1 1 1 −1 −1 1 1 −1 1 −1	1 4 4 1 4 1 −5 −5 4 −5 4 −5 1	82.29 percent
15	1 1 1 1 1 1 −1 1 −1 −1 1 1 −1 −1 −1	4 4 −5 4 −5 1	86.81 percent
16	1 1 1 1 1 1 −1 1 −1 1 −1 −1	3 21 45 39 27 5 −27 39 −45 21 −3 −25 43 37 −43 −25	79.43 percent

While the optical excitation is binary phase coded in accordance to weighting sequence c_k in table 1, one can choose to use Matched Filtering (weighting sequence c_k in table 1) or MisMatched filtering (weighting sequence w_k in table 1) as the 300 reference signal in figure 3(b) to calculate the binary phase code amplitude, peak delay time, and phase images using the method illustrated in the block diagram of thermal wave radar or thermophotonic radar imaging modality (shown in Figure 3(b)). The advantage of MisMatched filtering over Matched filtering is the significant reduction of side lobes at the expense of lower SNR[10].

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The binary phase code signal, *f(t)*, consists of a single frequency carrier, *C(t)*, and a binary coded envelope, *E(t)*. The signal is formed by either multiplying these components in the time-domain or alternatively by convolving their spectra in the frequency-domain. In general, an arbitrary binary sequence can be defined as $a_j=[a_1, a_2,..., a_N]$. In the special case where the temporal length of each code element equals the period of the carrier (T_o), the binary coded envelope can be modeled as a series of rectangular pulses of width T_o and height a_j shifted in the time axis by *(j-0.5)* T_o. Therefore, starting with the Fourier transform of a pulse, the analytical spectrum of the binary coded envelope can be obtained using the time-frequency shifting property of the Fourier transform:

$$\Im\{E(t)\} = E(\omega) = \frac{\sqrt{2\pi}}{\omega_o} Sinc\left(\frac{\omega}{\omega_o}\right) \sum_{j=1}^{N} a_j \exp\left[-i\omega T_o (j-0.5)\right] \qquad (5)$$

where ω_o and i are the carrier angular frequency and the imaginary unit, respectively. Finally, the analytical spectrum of the binary phase coded signal can be calculated through the convolution of equation (5) and the spectrum of the carrier waveform:

$$\Im\{f(t)\} = F(\omega) = \frac{\pi}{i\omega_o} \sum_{j=1}^{N} \left[a_j Sinc\left(\frac{\omega-\omega_o}{\omega_o}\right) \exp\left[-iT_o (j-0.5)(\omega-\omega_o)\right] - a_j Sinc\left(\frac{\omega+\omega_o}{\omega_o}\right) \exp\left[-iT_o (j-0.5)(\omega+\omega_o)\right] \right]$$

(6)

Equation (6) suggests that the spectrum of the binary coded signal consists of a series of weighted "sinc" functions yielding a narrow-band waveform with most of its energy located at the carrier frequency (narrow-band signal).

The thermophotonic response (Planck radiation emission) of a non-opaque turbid medium to a binary phase code excitation can be obtained through coupling of the optical and thermal-wave fields, where the total optical field (coherent + scattered)

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is the source of thermal-wave generation. As a simple example, the response of black body absorbers in a turbid medium is investigated. That is, the binary phase code excitation is applied to the surface (z=0) of a turbid medium with known scattering and absorption coefficients (μ_s and μ_a, respectively), where, after interaction with the turbid medium, the attenuated light is completely absorbed at $z=l$ and thermal waves are generated. The energy fluence, $I(z)$, of the one-dimensional, uniform, collimated beam normally incident on a homogeneous scattering and absorbing medium has been calculated by Prahl *et al.*[7]. Using this approximation, the thermal-wave problem can be formulated by adding a depth dependent source term to the heat diffusion differential equation (due to absorption by the medium) as well as an attenuated heat source at $z=l$ through a boundary condition:

$$\begin{cases} \dfrac{\partial^2\theta(z;\omega)}{\partial z^2} - \sigma^2\theta(z;\omega) = -\dfrac{\mu_a}{k} I(z)F(\omega) \\ -k\dfrac{\partial\theta(z;\omega)}{\partial z}\Big|_{z=0} = 0 \qquad \text{(I)} \\ -k\dfrac{\partial\theta(z;\omega)}{\partial z}\Big|_{z=l} = I(l)F(\omega) \qquad \text{(II)} \\ \theta(z;\omega) = \Im\{T(z,t) - T_\infty\} \end{cases} \tag{7}$$

where k, α, and $F(\omega)$ are thermal conductivity, thermal diffusivity and the spectrum of the applied binary phase code excitation **Error! Reference source not found.**, respectively, and $\sigma=\sqrt{i\omega/\alpha}$ is the complex wavenumber. Solving the frequency-domain differential equation subject to the boundary conditions and considering an average value for the infrared absorption coefficient within the spectral range of the detector ($\bar{\mu}_{IR}$), the conductive heat transfer spectrum of the thermophotonic signal can be calculated as:

$$S_c(l;\omega) \propto \bar{\mu}_{IR}\int_0^l \theta(z;\omega)\exp(-\bar{\mu}_{IR}z)dz = \bar{\mu}_{IR}\left[\begin{array}{l} \dfrac{A}{\sigma-\bar{\mu}_{IR}}\left(\exp[(\sigma-\bar{\mu}_{IR})l]-1\right) - \dfrac{B}{\sigma+\bar{\mu}_{IR}}\left(\exp[-(\sigma+\bar{\mu}_{IR})l]-1\right) \\ -\dfrac{C}{\mu_{eff}+\bar{\mu}_{IR}}\left(\exp\left[-(\mu_{eff}+\bar{\mu}_{IR})l\right]-1\right) - \dfrac{D}{\mu_t+\bar{\mu}_{IR}}\left(\exp[-(\mu_t+\bar{\mu}_{IR})l]-1\right) \end{array}\right]$$

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(8)

However, the infrared emission captured by the detector is the superposition of (8) and the direct Planck emission from the black-body absorber, attenuated through the turbid medium (9).

$$S(l;\omega) \propto S_c(l;\omega) + \theta(l;\omega)\exp(-\bar{\mu}_{IR} l) \quad (9)$$

Equations (6) and (9) formulate the spectra of the applied binary phase coded excitation (i.e. the matched/mismatched filter) and the thermophotonic response of a subsurface absorber at depth l to such excitation, respectively. Consequently, one can calculate the matched-filter cross-correlation signal and its phase analytically as (3) and (4), respectively, or experimentally via the algorithm depicted in figure 3(b).

Figures 4(b) and 4(c) plot theoretical comparisons of the CC signals obtained from chirp (dashed lines) and binary phase coded (solid lines) modulation techniques. Optical and thermal properties of dental enamel were used as the properties of the turbid medium. The CC responses clearly show that binary phase code modulation significantly improves the axial resolution (FWHM of the main peaks) as well as the SNR. Moreover, the plots suggest that matched/mismatched filtering using phase modulation can exhibit energy localization normally encountered in propagating hyperbolic wave-fields. As a result, one can obtain localized information from absorbers at different depths by investigating the CC plots at the corresponding delay times or alternatively obtain iso-delay (iso-depth) images in a thermophotonic radar imaging system. Consequently, by scanning the image plane in the delay time axis one can obtain thermal coherence tomographic images and locally resolve absorbers in a diffuse field.

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In another example embodiment, the aforementioned systems and methods are employed for the detection and/or monitoring of teeth. Teeth (including enamel, dentin, root and or cementum) are an optically turbid medium, therefore when light enters the tooth it scatters and gets absorbed along its path. Optical extinction depth is defined as the effective depth within which the light can get absorbed and generates heat, including both absorption and scattering effects. Interpolating the enamel extinction coefficient from the IR spectrum of dental enamel reported by Jones and Fried, the optical extinction depth is roughly 250 μm for the 808-nm laser light. However, as photon absorption events are responsible for generating thermal signals, it is the optical absorption depth (~ 1 cm) that is the controlling factor, or, more precisely, a superposition of 1) a conduction heat transfer mode whose depth is controlled by the thermal-wave centroid determined by the optical extinction depth and thermal diffusion length; and 2) a radiation heat transfer mode whose depth is controlled by the optical extinction depth: When modulated optical excitation is absorbed inside the tooth, the subsequent heat generation gives two contributions to the infrared camera signal. First, an oscillatory heat distribution (thermal-wave) is formed at or near the surface within a thermal diffusion length (at the modulation frequency of the absorbed optical excitation) which will conductively reach the surface of the tooth and contribute to the camera signal in the form of a depth integral through infrared emission.

Second, direct thermal infrared (Planck) emission occurs from all absorption locations (surface and subsurface) with IR photon back-propagation through the enamel due to the 15 to 20 % transmittance of enamel in the mid-infrared region. Considering the speed of light and the thickness of enamel, the latter contribution is instantaneous and therefore there will be no phase shift between the direct infrared

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(Planck) emission responses received from different depths in the tooth. Consequently, it is believed that there will be no contrast contribution from this type of direct emission in the thermophotonic lock-in phase image; however, direct emission will contribute to the amplitude image contrast as these images are concerned with the amplitude of infrared emission (number of IR photons) received at a specific modulation frequency, a function of the local absorption coefficient and optical-to-thermal energy conversion efficiency.

On the other hand, the thermal-wave contribution to the infrared camera signal is not instantaneous as speed of propagation of heat is significantly smaller than that of light. As a result, absorption at different depths will result in different phase values at a fixed modulation frequency. Unlike pure thermal waves generated in opaque media, optically non-saturated photothermal waves carry optical as well as thermal information. The most important feature of thermal waves is that their effective penetration depth can be controlled through the modulation frequency:

$$\mu_{th}(f) = \sqrt{\alpha/\pi f} \qquad (10a)$$

and the signal carries optical absorption information from depths $d \leq \mu_{th}(f)$. When the optical extinction depth, $\mu_{ex}(\lambda)$ contribution to the thermal-wave distribution is taken into account, where λ is the wavelength of the optical excitation source, in the concept of the thermophotonic-wave centroid, $L(\omega,\lambda)$:

$$L^{-1}(\omega,\lambda) = \mu^{-1}{}_{th}(\omega) + \mu^{-1}{}_{ex}(\lambda) \qquad (10b)$$

Equation 10(b) comprises the physical principle on which thermophotonic lock-in imaging hinges. In equation 10(b), μ_{th}, μ_{ex}, α, and f are thermal diffusion length, optical extinction depth, thermal diffusivity, and modulation frequency, respectively.

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Therefore, as photothermal-wave generated infrared emission is the dominant source of contrast in thermophotonic lock-in phase images, one can control the imaging depth by adjusting the modulation frequency according to equation 10. Due to the small thermal diffusivity, α, of enamel, dentin and root cementum, the maximum thermal diffusion length (i.e. at modulation frequency ~ 1 Hz) is on the order of ~300 μm. Therefore, phase images are best used for detecting inhomogeneities at short subsurface distances within the enamel such as the early demineralization and carious lesions while amplitude images can be used to detect deep features due to the large optical absorption depth of enamel. Moreover, biofilm, surface stains and dental plaque which are expected, in principle, to produce contrast in the thermophotonic lock-in images, they will do so minimally and only in the image amplitude due to their transparency to 808nm NIR excitation source used in this study. The thermophotonic lock-in phase image is physically immune to thin surface absorbers as it is independent of the optical properties of the surface.

The same situation holds for thermal wave radar/thermophotonic radar and binary phase code imaging as well. That is, the cross-correlation amplitude images obtain contributions from both the conductive and direct emission sources while the cross-correlation peak delay time and phase images only receive contribution from the conductive part.

The preceding theoretical arguments related to mechanisms of photothermal generation in teeth and other non-opaque turbid matter are not intended to limit the scope of the embodiments disclosed herein. Moreover, although the above embodiments have been focusing on teeth, it is to be understood that the sample may be any suitable sample that is capable of generating detectable photothermal radiation. For example, sample 130 may be processed or finished material, where the methods

described herein are employed for non-destructive testing purposes, especially those that benefit from the characterization of subsurface absorption. These include, but are not confined to, subsurface cracks and defects in metals and coatings; automotive component inspection and quality assurance, including unsintered parts in the green state; aerospace component inspection such as gears and hardened steels, and the determination of the hardness case depth; optical and laser materials and coatings with visually imperceptible blemishes; coatings and alloys, biomedical materials and soft and hard tissue diagnostics, cracks and defects in dental restorations including direct placed and indirect fabricated prosthetics, defects or ill-fitting prosthetics linked to dental implants, defects at the margins or junctions of tooth and dental restorations, and all other materials applications to which photothermal diagnostics has been and can be applied[11]. In dental applications, cracks and defects in dental restorations including direct placed and indirect fabricated prosthetics, defects or ill-fitting prosthetics linked to dental implants, defects at the margins or junctions of tooth and dental restorations.

Additional applications of the preceding embodiments to the detection of defects in dental materials includes the following: detecting and monitoring the effect of various agents, treatments and therapies on in-vivo or in-vitro teeth or samples to determine whether or not they create lesions or erosions, stabilize these areas of tissue loss or promote regeneration of lost tissue; detecting and monitoring changes in tooth structure as additional evidence of various disease process such as bruxism, gastro-esophagel reflux, TemproMandibular Joint Dysfunction, and the like; detecting, examining and scanning a tooth surface whether intact or prepared for the placement of a direct or indirect restoration to ensure that the surface is clean, free of defects including cracks or accumulations of debris, cements, plaque etc. before

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placement of the restoration; detecting and monitoring defects and or dental caries around the edges of direct placed (amalgam, composite resin and other) dental materials; detecting and monitoring the integrity of dental materials including detection of cracks, craze lines etc. on both direct placed and indirect fabricated dental prosthetics; detecting and monitoring defects at the margins of dental sealants and caries beneath these dental sealants which are placed in the tooth; detecting and monitoring defects and or dental caries at the margins of indirectly placed dental restorations including full crowns, inlays, onlays, bridges etc. made of gold, composite and or porcelain or other dental materials; detecting, monitoring and confirming the fit and marginal integrity of direct and indirect placed dental materials into prepared tooth surfaces; detecting and monitoring the fit of precision attached dental restorations to ensure that the attachments are completely seated; detecting and monitoring the fit of mesostructures onto osseous integrated dental implants on initial placement and over the lifetime of the prosthesis; detecting and monitoring the integrity of materials used in the manufacture of dental prosthesis including osseous integrated implants, mesostructures and or superstructures, frameworks of fixed and removable prosthesis made of metal alloy, sintered porcelain and other materials; detecting and monitoring carious lesions and or defects around orthodontic brackets and other materials that are bonded on to the tooth surface not excluding bonded bridgework, veneers and retainers or other surface sealants; detecting the pulp chamber and or root canal system inside the tooth surface while performing endodontic therapy; confirming the marginal integrity of the endodontic obturation or filling of the root canal system of a tooth; detecting cracks both on the outside of the tooth surface and from within a cavity preparation or within the confines of the pulp chamber or root canal system; detecting and examining the anatomical structure of

root apices while performing surgery in this area; detecting, examining and locating neurovascular bundle while performing surgery in the maxilla and or mandible; detecting and monitoring the recession or movement or migration of the gingival tissue from the CEJ; detecting and monitoring the evolution of erosion lesions or lesions due to the exposure of acids on the tooth surface or surface of the dental restorative materials; detecting and monitoring the evolution of carious lesions or erosion lesions and how various therapies can enhance, stabilize or reduce lesions size; and incorporating this into a preventive based program that can be used in a clinical practice or a public health programme; combining the images, information into a data base that is patient specific, specific for a particular dental practice, for a particular age group, particular group of teeth, particular sex or ethnic group or particular postal code or geographic region to provide information on the health and status of the teeth, prosthesis or other entities studied; taking the combined images and information from this data base to provide historical information and or epidemiologic information on the caries present, size of lesion, state of dental materials in various environments, and other information on the oral health and integrity of the dental materials and prosthetics; taking the combined images and information from this data base on a patient specific, gender specific or other groupings and comparing it against known risk factors for caries, erosion, bruxism and other oral disorders and conditions to develop a risk profile or risk ranking for a patient or a population group; using the information in this data base to provide guidance on the various therapies, pathologic situations to patients, oral health providers, providers of the various dental programs and manufacturers of the various therapies; and detecting and monitoring the integrity of various dental instruments including but not limited to dental burs, diamond dental burs, surgical elevators,

endodontic files and instruments and or dental scalers and or curettes to ensure that there are no defects that would affect the integrity of the material or instrument while it is being used during a procedure.

The following examples are presented to enable those skilled in the art to understand and to practice embodiments of the present disclosure. They should not be considered as a limitation on the scope of the present embodiments, but merely as being illustrative and representative thereof.

EXAMPLES

Example 1: Early Detection of Dental Caries

In order to apply controlled demineralization to tooth samples, a demineralizing / artificial caries solution was prepared. The solution was an acidified gel, consisting of 0.1 M lactic acid gelled to a thick consistency with 6% w/v hydroxyethylcellulose and the pH adjusted to 4.5 with 0.1 M NaOH. Demineralization with acidified gel approximates the natural carious lesion as it mimics the properties of actual dental plaques in the oral cavity. Previous studies show that this solution can produce a subsurface lesion in enamel with a sound surface layer which is characteristic of an early carious lesion[1].

As it was desired to observe the contrast between demineralized and healthy areas in a whole tooth, a treatment protocol was followed in which the interrogated surface of the sample was covered with two coatings of commercial transparent nail polish except for a rectangular or square window, henceforth referred to as the treatment window. The demineralization on the window was carried out by submerging the sample upside down in a polypropylene test tube containing 30 ml of demineralizing / artificial caries solution. After the treatment period the sample was removed from the gel, rinsed under running tap water for approximately 1 minute and dried in air for 5

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minutes. Then, the transparent nail polish was removed from the interrogated surface with acetone and the sample was again rinsed, dried, and stored in the air-tight humid box for at least 24 hours before the imaging. For consecutive demineralization, after the imaging step the sample was again covered with the transparent nail polish (except for the treatment window) and treated / demineralized for additional days in order to investigate the progression of demineralization and evolution of the artificial carious lesion with time.

Figure 5(a) shows an optical image of sample A1 before application of demineralization in the treatment window. The dashed rectangle in this figure shows the area that was imaged using the thermophotonic lock-in system while the solid rectangle depicts the location of the treatment window. The optical image shows traces of a discontinuity on the surface of enamel (feature 1). The two vertical lines on the root area show the approximate lateral position of the treatment window (solid rectangle). These lines were meant to aid the operator with sample alignment and are of no scientific importance. Figure 5(b) "F" shows the dental radiograph of the untreated sample ("before") at the same view as the optical image and figure 5(b) "S" shows the side view indicated by the arrow in the optical image (Fig. 5(a)). Based on these radiographs and visual examination sample A1 was a healthy tooth before application of artificial caries treatment and it is interesting to see that the discontinuity or crack on the enamel surface (feature 1) could not be resolved in either of the dental radiographs.

Figures 5(b-c) and 5(d) are the x-ray radiographs and the optical image, respectively, taken from sample A1 after 10 days of treatment. None of these images can show even a trace of mineral loss in the treatment window, showing the insensitivity of conventional clinical diagnostic methods to early demineralization or

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carious lesion formation. Figure 5(e) depicts the thermophotonic lock-in phase image of sample A1 taken at 10 Hz before application of any treatment. This image not only shows the enamel discontinuity observed in the optical image (feature 1) but also reveals the presence of a vertical crack (feature 2) and the cementoenamel junction (CEJ, feature 3). Neither the x-ray radiographs (Fig. 5(b)) nor the optical image (Fig. 5(a)), could resolve this vertical crack (feature 2). The reason of the high sensitivity of thermophotonic images to cracks is the fissured nature of cracks which enhances the photothermal temperature field through thermal-wave flux localization generating high contrast.

The appearance of the enamel discontinuity in the phase image (feature 1 in Fig. 5(e)) has similar physical origin to that of cracks. It was postulated that feature 1 was caused by the forces applied during the tooth extraction. The appearance of a dark band in the phase images of figure 5 (feature 3) at the CEJ level suggests the presence of a border between enamel and cementum, remnants of periodontal ligament at this position. According to the dental literature, enamel of the cervical margin of the tooth is one of the locations which favors plaque formation and is therefore prone to demineralization. It can be seen that all the thermophotonic phase images of figure 5 can detect feature 3 (the CEJ) with high sensitivity (contrast). In fact, one of the most important advantages of thermophotonic lock-in imaging compared to single point photothermal radiometric (PTR) measurements is the significant improvement in the wealth of data resulting in excellent contrast and reliability of the results in real time and in direct comparison with conventional dental radiographs. Point-by-point measurements would require much longer time spans to produce surface images, which would be impractical in clinical applications.

Figures 5(f) to 5(i) show the phase images taken at 2, 4, 8, and 10 days of

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treatment (mineral loss only within the treatment window), respectively. It should be noted that the same contrast mapping (linear, with identical thresholds) has been used in all thermophotonic lock-in images of figure 5 to ensure the validity of comparison between the images. It can be observed that as treatment time increases the treated window becomes more apparent while the other features in the images remain more or less the same. The mean phase values within the treatment window (empty rectangle in Fig. 1(e)) for the untreated, 2D, 4D, 8D, and 10D samples are found to be -7.47°, -25.22°, -31.75°, -42.07°, and -49.66°, respectively. This monotonic decrease in the phase lag is due to the progression of the lesion into the enamel. As the lesion thickness increases, the thermal-wave centroid shifts closer to the surface, thereby decreasing the phase lag between the applied optical excitation and the received infrared response. The phase lag decreases also with respect to the intact state ("before").

Feature 4 in figure 5(f) is most probably a material inhomogeneity formed as a result of incomplete removal of nail polish from the enamel surface after the second day of demineralization. The feature disappeared after the next demineralization cycle. It appears that feature 5 is stress-induced cracks that were formed during tooth extraction. The cracks become more apparent toward the later stages of demineralization (Figs 5(e) to 5(i)) due to successive nail polish penetration into them. It has been known that nail polish can penetrate tens of micrometers into dental enamel[2].

Figure 5(j) is a plot of transverse profiles of the phase images along the dashed line shown in figure 5(i). The dashed vertical lines represent the location of the treatment window (centered at 6.27 mm). It can be seen that as demineralization progresses, the absolute thermophotonic phase values increase within the treatment

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window but remain approximately the same outside the treatment window. Furthermore, examination of these phase profiles reveals that the demineralization and artificial lesion has not only propagated vertically into the enamel but has also spread out laterally. However, the extent of the lesion is always maximal within the treatment window and decreases rapidly laterally away from the treatment window. The two dips in the phase values at ~3.9 mm and ~8.8 mm lateral positions are related to the vertical defects at those locations (features 2 and 1, respectively).

Figure 5(k) represents the transverse micro-radiographic mineral profile vertically along the center of the treatment window. Mean lesion depth of 326.4 μm and mineral loss of 5,710 vol% μm was reported by the transverse micro-radiographic software for the lesion produced at the center of the treatment window. It can be seen that the lesion retains a relatively well-preserved surface layer with a moderate mineral loss over a large depth. It is somewhat surprising to find such a deep lesion formed after only 10 days of treatment with the artificial caries gel, but it is a well-known fact that the rate of demineralization can vary greatly among teeth[1].

Figure 6 presents the results obtained from sample A2. Unlike Sample A1, the occlusal surface was investigated for this sample. Figure 6(b) shows the thermophotonic lock-in amplitude image taken at 10 Hz. The amplitude image shows the presence of caries at several locations but the image is rather diffuse. Using this image, four regions of interest (i, f, g, and h) were identified within the imaged area of the optical image (Fig. 6(a)). The thermophotonic lock-in phase image taken at 10 Hz is shown in figure 6(c). No feature can be resolved in the blurry phase image. The reason for such poor resolution is the relatively long, diffusion-limited thermal wavelength at 10 Hz. In fact, in these images the contributions from deeper features have resulted in nuisance interferences superposed on features closer to the surface.

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Consequently, to avoid the interfering effects of deep features, it was decided to reduce the thermal wavelength by generating the images at 100 Hz in order to be able to effectively detect the areas of mineral loss in the pits and fissures of the occlusal surface and the near-subsurface regions. The resolution improvement at higher frequencies is a well-known behavior of thermal-waves[3] and is clearly visible in the amplitude and phase images obtained at 100 Hz (Figs 6(d) and 6(e)). The pits labeled *f, g,* and *h* in figure 6(e) are shown as carious spots, whereas the groove labelled *i* is shown as a healthy bright spot (similar to intact regions in images 5b to 5f). Transverse micro-radiographic profiles are shown in Figures 6i-f of the dark carious regions *f, g,* and *h* and of the groove *i*, clearly show the presence of mineral losses at points *f, g* and *h* while no significant mineral loss can be observed in the mineral profile obtained at *i*. The transverse micro-radiographic profiles fully validate the results of the non-contacting, non-destructive imaging method.

Example 2a: Non-destructive testing of engineering materials with subsurface absorbers and early detection of dental caries using thermophotonic radar imaging

The physical principles of light absorption/scattering and thermal-wave generation are the same for the various imaging modalities disclosed herein. The difference lies in the applied optical excitation pattern and the subsequent signal processing algorithm. As discussed above, in thermal wave radar (or thermophotonic radar) imaging a chirp excitation is used instead of a single frequency modulation. As a result, according to equation 5a, the thermal diffusion length is not fixed and the generated thermal-waves dynamically scan a series of depths. One of the problems encountered in thermophotonic lock-in imaging is the compromise one needs to make between the maximum detection depth and the depth resolution. While the low

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frequency thermal-waves can see deep into the sample, they lack the desired depth resolution; the high frequency thermal-waves, on the other hand, have the exact opposite situation due to the reduced thermal diffusion length.

In order to experimentally investigate the capabilities of the thermophotonic radar method, three samples of engineering and biological materials were designed and prepared. The first sample, B1 400 (Figure 7(a)), is a black plastic step-wedge sample (step height = 200 μm) placed inside a scattering medium (polyvinyl chloride-plastisol (PVCP) with added Titanium dioxide (TiO_2) powder for scattering[6]) such that the first step is located approximately 1 mm below the phantom surface. The second sample, B2 420 (Figure 7(b)), was made using 120 μm-thick Fisher Scientific borosilicate microscope cover slips. The glass was covered by commercial green 430 (on the left) and black 440 (on the right) paints with no paint applied to the center part 450 to form a three-strip pattern. Six additional microscope cover slips were put on the painted slip to simulate 2 absorbers with different absorbing coefficients 720 μm below the surface. To show the application of the Thermophotonic Radar imaging in the dental field, the third sample, B3 460, was chosen to be an extracted human tooth that was locally demineralized using the artificial caries acidic gel within two square shape treatment windows 470, as shown in figure 7(c). The left and right windows were treated / demineralized for 10 and 20 days, respectively.

Figure 8 shows the results obtained from a comparison study on the depth resolution capabilities of thermophotonic lock-in and thermophotonic radar imaging involving sample B1 (FIG. 7(a)). Figures 8(a) and 8(d) show the thermophotonic lock-in phase image obtained at 0.01 Hz and its mean horizontal phase profile, respectively. It can be seen that due to the very large thermal diffusion length at such low modulation frequency it is impossible to resolve the 200-μm-high steps from each

other and as a result the phase image appears as a gradient of colors between the two color bar extremes.

Figure 8(b) shows the thermophotonic lock-in phase image obtained at 1 Hz. The bar plot of figure 8(e) depicts the mean phase values on each step along with their standard deviations. The error bars indicate that statistically only the first two steps can be resolved. Figures 8(a) and (b) clearly show the maximum detection depth/depth resolution trade-off of thermophotonic lock-in imaging.

Figure 8(c) is a CC amplitude image obtained from 0.01-1Hz chirps with duration of 6s (using the exact same experimental conditions as those used for Figures 8(a) and 8(b)) and figure 8(f) depicts the mean CC values on each step. It can be seen that the thermophotonic radar imaging not only resolves the steps but also detects them all. These advantages are due to the fact that the matched filtering/cross correlation process puts most energy of the signal under its main narrow peak, improving depth resolution and greatly enhancing the signal to noise ratio, which equals the time (chirp duration) – bandwidth (chirp frequency content) product, thereby improving maximum detection depth.

Figure 9 depicts the results involving sample B2 (FIG. 7(b)) to compare the three contrast parameters that can be used in thermophotonic radar imaging. Figures 9(a), 9(b), and 9(c) are the images obtained using cross correlation amplitude, peak delay time, and phase, respectively, and figures 9(d), 9(e), and 9(f) show their horizontal mean profiles. It can be seen that the amplitude channel is truly reflecting the amount of energy absorption by the two equally deep absorbers (green and black paints), yielding significantly different CC amplitude values from them. Consequently, the amplitude channel is not a true measure of the depth of the absorber while the CC peak delay time and phase values are truly linked to the depth

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of the absorbers as they maintain the same value over the two absorbers regardless of their absorption coefficient (similar to thermophotonic lock-in phase channel). However, in terms of SNR the CC amplitude channel is significantly stronger than peak delay time and phase channels and therefore it may be beneficial to use the amplitude images to complement the information obtained from the phase and peak delay time images.

Figures 10(a)-(c) show the CC amplitude, peak delay time, and phase images obtained from sample B3. In general, tooth demineralization results in more porosity and leads to more light absorption and scattering that consequently increases the amplitude of thermal-waves and shifts the thermophotonic centroid of Eq. 5b (i.e. phase shift) compared to healthy spots. As a result, the artificially created caries is clearly detectable in all CC images (FIGs 10(a)-(c)). However, due to the emissivity-normalized nature of peak delay time and phase channels, more details can be resolved in figures 10(b) and (c) compared to figure 10(a). The higher contrast of the right treatment window indicates a greater mineral loss due to the additional treatment days. On the other hand, thermophotonic lock-in phase images suffer from low depth resolution at 0.01Hz (FIG 10(d)): they cannot probe deep enough at 1Hz (FIG 10(e) and cannot show the additional mineral loss in the right treatment window). Figure 10(f) depicts the transverse micro radiography mineral profiles along points 1-3 depicted in figure 10(c) and are provided as proof of mineral loss within the treatment windows.

Additional applications to engineered automotive and aerospace materials are in detecting metal hardness case depth and case depth non-uniformities using a thermophotonic radar image of the cross-correlation peak delay times which correspond to case hardness depth[12].

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Example 2b: Non-destructive testing of engineering materials with subsurface absorbers and early detection of dental caries using binary phase code Imaging

Table 1 (shown above) includes the binary phase codes up to 16 bits. These codes are used as an envelope of a single-frequency modulated signal to yield the reference signal for binary phase code imaging.

Samples B1 and B3 (Figure 7(a) and (c)) were used to study the capabilities of binary phase code imaging. Figure 11 shows the results obtained from sample B1 using a 7-bit binary phase coding on a 1Hz carrier signal (Figures 11 (a) and (c)) as well as those of thermophotonic lock-in imaging at 1Hz (Figures 11 (b) and (d)). It can be seen that due to the advantages of matched filtering/cross-correlation the binary phase code image resolves all the steps while the thermophotonic lock-in image can statistically detect only the first two steps. That is, binary phase code imaging has a significantly better depth resolution compared to thermophotonic lock-in imaging.

Figure 12 shows a similar comparison but on an extracted tooth sample (sample B3, figure 7(c)). While the thermophotonic lock-in amplitude image appears too blurry and the thermophotonic lock-in phase image shows only traces of mineral loss within the treatment windows, the emissivity normalized binary phase code peak delay time and phase images not only detect the regions of mineral loss but also show the additional mineral loss of the right window compared to that of the left window.

Figure 13 depicts a well-known limitation and challenge of diffusion fields: resolving stacked overlapping defects. Figure 13(a) shows an exploded view of a cross-shaped sample made of two strip absorbers. The deeper strip is a black plastic

sample completely absorbing the optical flux, while the shallower strip is a partially absorbing phantom. All other components are transparent polyvinyl chloride-plastisol.

When viewed from the top, the cross sample covers all possible combinations: absorbers at two different depths (the end sections of the absorbing strips, points 1 and 2 in Fig 13(b)) and two absorbers on top of each other (point 3 in Fig 13(b)). Figures 13(b) and 13(c) show the thermophotonic lock-in amplitude and phase images of this sample, respectively. It can be observed that the amplitude image cannot distinguish between the deeper and shallower absorbers (vertical and horizontal strip, respectively). However, the amplitude information can be used to extract and process only those pixels having a high value (i.e. a subsurface absorber). Although the thermophotonic lock-in phase image yields significantly different values over the single absorbers (points 1 and 2) it cannot detect the layered structure of point 3. The axial resolution of both amplitude and phase images is limited by the depth-integrated nature of thermal waves.

Figures 13 (d) and (e) are the binary phase code peak delay time images using the temporal data of points 1 and 2 as the matched filter, respectively. When using the temporal camera data of point 1 as the matched filter, all the diffusion waves originating at the same depth as that of point 1 will have their CC peaks located at $\tau = 0$ (correlogramic image).

A similar situation arises in figure 13(e) for diffusion waves from the shallower absorber using the temporal camera data of point 2 as the matched filter. The fact that the layered structure of point 3 shows a maximum correlation to both data of points 1 and 2 ($\tau_p = 0$) shows that matched-filter binary phase code imaging can resolve the layered structure axially.

This depth resolved phenomenon is normally a property of propagating

hyperbolic wave-fields and not of parabolic (diffusive) fields. The implications of correlogramic imaging can open a new field of generating layer-by-layer subsurface thermal coherence tomography (TCT) using naturally incoherent diffusion waves.

Accordingly, according to some embodiments, correlographic imaging may be employed to produce images at constant delay times. Since each delay time corresponds to a given depth, by making the images at different delay times one can make slice by slice images. The example shown in Figure 13 provides experimental demonstration that this method provides depth selective (depth slice) images. Although such images may also be produced using chirped waveforms, binary phase coded waveforms generally provide superior axial resolution.

An illustration of the capabilities of this correlographic binary phase code imaging modality applied to turbid media thermophotonics (biological tissue) is its ability to detect early caries in human teeth which conventional clinical diagnostic modalities, like radiographs, cannot detect. Early caries remove mineral from areas very close to the enamel surface and create micro-pores which trap light photons and eventually promote close-to-surface light absorption/thermal-wave generation. As a result, thermal-waves from early caries travel less distance to reach the interrogated surface and yield higher amplitude and smaller phase lag/delay compared to those of intact regions.

However, an important shortcoming of dental thermophotonic lock-in imaging is its inability to detect interproximal (in between teeth) caries when inspected from the accessible buccal (front) surface. A comparison of thermophotonic lock-in and binary phase code phase images of figure 14(b) and 14(c) under identical experimental conditions, shows how the enhanced axial resolution of the binary phase code imaging can resolve deep interproximal caries. Moreover, by constructing

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images (such as amplitude or phase images) at given delay times one can perform depth-selective slicing (thermal coherence tomography) in the turbid medium to resolve the defective regions, figure 14(e), from the intact areas, figure 14(f).

Figure 15(a) shows the optical image of the interrogated surface of a goat bone along with its cross section. The optical image shows that the spongy trabecular bone is covered by the more dense cortical bone on the surface. Figure 15(b) is the phase image obtained using the binary phase code technique. The low carrier frequency of 1 Hz ensures penetration of thermal-waves into the trabecular structure, while the depth-resolved nature of phase modulated matched filtering reveals the trabecular structure that lies right below the cortical overlayer.

Figure 15 demonstrates that the depth-selective thermophotonic radar imaging methods disclosed herein are potentially suitable for the imaging of bone structure. Such imaging can be employed to support the identification of bone osteoporosis, and in particular, early bone osteoporosis. Indeed, the present example imaging methods could be employed for screening of osteoporosis. For example, the measured image may be processed according to known image processing techniques to identify abnormal bone condition, such as, by generating, based on the image, a measure of bone health, and comparing the measure to thresholds, normal ranges, or other calibration parameters. It is noted that at present, direct expenditures for treatment of osteoporotic fracture in the U.S. are estimated at $10 – $15 billion annually, and that no imaging methodology currently exists for the early diagnosis of osteoporosis.

Additional applications to engineered automotive and aerospace materials are in detecting metal hardness case depth and case depth non-uniformities using a binary phase code image of the cross-correlation peak delay times which correspond to case hardness depth[12].

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The specific embodiments described above have been shown by way of example, and it should be understood that these embodiments may be susceptible to various modifications and alternative forms. It should be further understood that the claims are not intended to be limited to the particular forms disclosed, but rather to cover all modifications, equivalents, and alternatives falling within the spirit and scope of this disclosure.

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THEREFORE WHAT IS CLAIMED IS:

1. A method of performing thermophotonic imaging, said method comprising the steps of:

providing a sample;

providing an optical source having a wavelength selected to generate photothermal radiation within said sample;

providing an imaging camera with an optical bandwidth selected for detection of said photothermal radiation;

generating a reference waveform comprising a plurality of modulation cycles;

producing a modulated optical beam by modulating an intensity of an optical beam emitted by said optical source according to said reference waveform;

illuminating said sample with said modulated optical beam;

imaging said photothermal radiation with said imaging camera;

recording a plurality of dynamically averaged image frames at time offsets corresponding to different values of said reference waveform; and

processing said dynamically averaged image frames and said reference waveform to obtain an image relating to said photothermal radiation.

2. The method according to claim 1 wherein said dynamically averaged image frames are obtained according to the following steps:

recording a plurality of image frames at times corresponding to different values of said reference waveform;

repeating, one or more times, said step of recording said image frames at times corresponding to different values of said reference waveform, and dynamically

averaging said recorded image frames for each said different value of said reference waveform, thereby obtaining dynamically averaged image frames.

3. The method according to claim 2 wherein said step of recording said plurality of image frames at different values of said reference waveform comprises recording said plurality of image frames over a single modulation cycle/correlation period.

4. The method according to claim 2 wherein said plurality of image frames at different values of said reference waveform are obtained over more than one modulation cycle.

5. The method according to claim 4 wherein a frame acquisition rate of said imaging camera is less than a modulation frequency of said reference waveform.

6. The method according to claim 2 or 3 further comprising the step of recording, for each image frame of said plurality of image frames, a substantially instantaneous value of said reference waveform.

7. The method according to claim 6 further comprising the step of generating a quadrature waveform based on said reference waveform, and recording, for each image frame of said plurality of image frames, a substantially instantaneous value of said quadrature waveform.

8. The method according to any one of claims 1 to 7 further comprising the step of generating an integration pulse train comprising a series of pulses, wherein each

pulse is generated at a time at which an image frame is acquired by said imaging camera, wherein said step of generating of said reference waveform is triggered according to said integration pulse train.

9. The method according to claim 8 wherein said integration pulse train is generated by said imaging camera.

10. The method according to any one of claims 1 to 9 further comprising the step of generating a flag pulse train comprising a series of pulses, wherein each pulse is generated at a commencement of a given modulation cycle/correlation period, and identifying one or both of a beginning and an end of said given modulation cycle/correlation period according to said flag pulse train.

11. The method according to any one of claims 1 to 10 wherein a modulation frequency of said reference waveform is greater than approximately 0.01 Hz.

12. The method according to any one of claims 1 to 11 wherein said reference waveform comprises a single frequency and wherein said image is obtained by lock-in processing.

13. The method according to claim 12 wherein said step of processing said dynamically averaged image frames and said reference waveform comprises, for each pixel in said image, performing the steps of:

multiplying said dynamically averaged image frames by said reference waveform to obtain in-phase product values; and

summing said in-phase product values to obtain an in-phase sum;

generating a quadrature waveform based on said reference waveform;

multiplying said dynamically averaged image frames by said quadrature waveform to obtain phase-shifted product values; and

summing said phase-shifted product values to obtain a phase-shifted sum.

14. The method according to claim 13 wherein said image is an amplitude image, and wherein said processing further comprises calculating a magnitude of a complex quantity based on said in-phase sum and said phase-shifted sum.

15. The method according to claim 13 wherein said image is a phase image, and wherein said processing further comprises:

calculating a phase angle of a complex quantity based on said in-phase sum and said phase-shifted sum.

16. The method according to any one of claims 1 to 11 wherein said reference waveform comprises multiple frequency components.

17. The method according to claim 16 wherein said reference waveform comprises a frequency chirp.

18. The method according to claim 16 wherein said reference waveform is a binary phase coded waveform.

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19. The method according to any one of claims 16 to 18 wherein said image is a cross-correlation peak amplitude image obtained by the steps of:

obtaining a complex cross-correlation signal of said reference waveform and each pixel of said dynamically averaged image frames; and

determining, for each said pixel, a peak amplitude value of a peak in a real part of said cross-correlation signal.

20. The method according to any one of claims 16 to 18 wherein said image is a cross-correlation peak delay image obtained by the steps of:

obtaining a complex cross-correlation signal of said reference waveform and each pixel of said dynamically averaged image frames; and

determining, for each said pixel, a delay of a peak in a real part of said complex cross-correlation signal.

21. The method according to any one of claims 16 to 18 wherein said image is a cross-correlation phase image obtained by the steps of:

obtaining a first complex cross-correlation signal of said reference waveform and each pixel of said dynamically averaged image frames;

obtaining a second complex cross-correlation signal of a quadrature waveform and each pixel of said dynamically averaged image frames, wherein said quadrature waveform is based on said reference waveform;

forming a complex quantity comprising a real portion of first complex cross-correlation signal and a real portion of said second complex cross-correlation signal; and

obtaining said phase image by determining, for each pixel, a phase angle of said complex quantity at a pre-selected time delay.

22. The method according to any one of claims 1 to 21 wherein said sample is selected from the group consisting of automotive components, aerospace components, an optical material, a laser material, a biomedical material, and a biological tissue.

23. The method according to any one of claims 1 to 22 wherein said sample is a material comprising one or more of a subsurface crack and a delamination.

24. The method according to any one of claims 1 to 21 wherein said sample is an unsintered component in a green state.

25. The method according to any one of claims 1 to 24 further comprising the step of determining a case hardness depth.

26. The method according to any one of claims 1 to 21 wherein said sample is a dental sample, the method including the step of displaying the image.

27. The method according to any one of claims 1 to 21 wherein said sample is a dental or medical instrument.

28. The method according to any one of claims 1 to 21 wherein said sample includes bone, wherein the step of imaging the photothermal radiation with the imaging camera includes imaging photothermal radiation generated within the bone.

29. The method according to claim 28 wherein the bone is covered with tissue, and wherein the optical source is configured for transmitting at least a portion of the incident optical beam through the tissue for the generation of the photothermal radiation within the bone.

30. The method according to claim 28 or 29 further wherein a modulation frequency of the modulated optical beam is selected to support penetration of the photothermal radiation within a trabecular structure of the bone.

31. The method according to any one of claims 28 to 30 further including the step of identifying an onset or presence of osteoporosis in the bone based on the image.

32. The method according to claim 26 further wherein said dental sample is a tooth sample or whole groups of teeth.

33. The method according to claim 26 wherein the dental sample is a tooth, the method further comprising the step of analyzing said image to determine one or more of a presence and a location of demineralization, erosion or dental caries in said tooth.

34. The method according to claim 26 further comprising the step of monitoring an evolution of one or more of demineralization, erosion and dental caries by comparing said image to one or more other images.

35. The method according to claim 26 wherein the image is a first image, the method further comprising the step of obtaining additional image of the dental sample after a time delay, and comparing the first image to the additional image for monitoring changes in the dental sample.

36. The method according to claim 26 wherein the image is a first image, the method further comprising the step of applying a treatment or therapy to said dental sample, obtaining additional image, and comparing the first image to the additional image to assess an efficacy of the treatment or therapy.

37. The method according to claim 26 wherein the dental sample is a tooth surface that is prepared for prepared for placement of a direct or indirect restoration, the method including the step of confirming, based on the image, suitability of the tooth surface for placement of the restoration.

38. The method according to claim 26 wherein the dental sample includes a tooth having a dental material placed directly thereon, wherein the image includes a region around an edge of the dental material for detecting or monitoring a defect around the edge of the material.

39. The method according to claim 38 wherein the dental material is a dental sealant.

40. The method according to claim 26 wherein the dental sample includes a tooth having a dental prosthetic, wherein the image includes the dental prosthetic for detecting or monitoring a defect associated with the dental prosthetic.

41. The method according to claim 26 wherein the dental sample includes a tooth having a dental restoration attached thereto, wherein the image includes the dental restoration for detecting or monitoring the attachment of the dental restoration.

42. The method according to claim 26 wherein the dental sample includes a dental implant, wherein the image includes the dental implant for detecting or monitoring the integrity of the dental implant.

43. The method according to claim 26 wherein the image includes at least one of the pulp chamber and root canal system of the dental sample.

44. The method according to claim 26 wherein the image includes the anatomical structure of root apices or the neurovascular bundle.

45. The method according to any one of claims 1 to 44 further comprising the step of identifying a defect region in the image.

46. The method according to claim 45 further comprising the step of displaying the defect region in a colour associated with the defect region.

47. The method according to claim 46 wherein the colour is associated with a relative size of the defect region.

48. The method according to claim 27 wherein said dental or medical instrument is selected from the group consisting of endodontic instruments, catheters and other indwelling instruments.

49. The method according to any one of claims 1 to 47 wherein said wavelength is selected to lie within a range of approximately 600 nm to 2000 nm.

50. The method according to any one of claims 1 to 47 wherein said imaging camera is selected to have a spectral response overlapping with at least a portion of the mid-infrared spectrum.

51. A system for performing thermophotonic imaging, said system comprising:

an optical source having a wavelength selected to generate photothermal radiation within a sample;

an imaging camera with an optical bandwidth selected for detection of said photothermal radiation, wherein said imaging camera is configured to acquire image frames a given frame rate and output an integration pulse train comprising a series of pulses, each pulse corresponding to a time at which an image frame is acquired by said imaging camera;

a waveform generating system for generating a reference waveform, wherein an output of said waveform generating system is connected to an input of said optical source for modulating an intensity of an optical beam emitted by said optical source;

a processor programmed to dynamically average image frames obtained by said imaging camera, and to process said dynamically averaged image frames, said

reference waveform and a quadrature waveform based on said reference waveform, to provide one or more of an amplitude image and a phase image; and

a memory for storing dynamically averaged image frames.

52. The system according to claim 51 wherein a modulation frequency of said reference waveform is greater than approximately 0.01 Hz.

53. The system according to claim 51 wherein said imaging camera comprises a frame acquisition rate that is less than a modulation frequency of said reference waveform.

54. The system according to any one of claims 51 to 53 wherein said wavelength lies within approximately 600 nm to 2000 nm.

55. The system according to any one of claims 51 to 54 wherein a spectral response of said imaging camera overlaps at least a portion of the mid-infrared spectrum.

56. A method of performing thermophotonic imaging, said method comprising the steps of:

providing a sample;

providing an optical source having a wavelength selected to generate photothermal radiation within said sample;

providing an imaging camera with an optical bandwidth selected for detection of said photothermal radiation;

generating a reference waveform comprising a binary phase coded waveform having a plurality of modulation cycles;

producing a modulated optical beam by modulating an intensity of an optical beam emitted by said optical source according to said reference waveform;

illuminating said sample with said modulated optical beam;

imaging said photothermal radiation with said imaging camera;

recording a plurality of dynamically averaged image frames at time offsets corresponding to different values of said reference waveform; and

processing said dynamically averaged image frames and said reference waveform to obtain an image relating to said photothermal radiation.

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Mod. in 170
LASER SYSTEM
140
120
In. Ref. 160
DATA ACQUISITION SYSTEM
Quad ref. 165
Camera
Flag Pulse 175
130
IT Pulse 190
110
COMPUTING SYSTEM
Image sequence 180
100
150

Figure 1

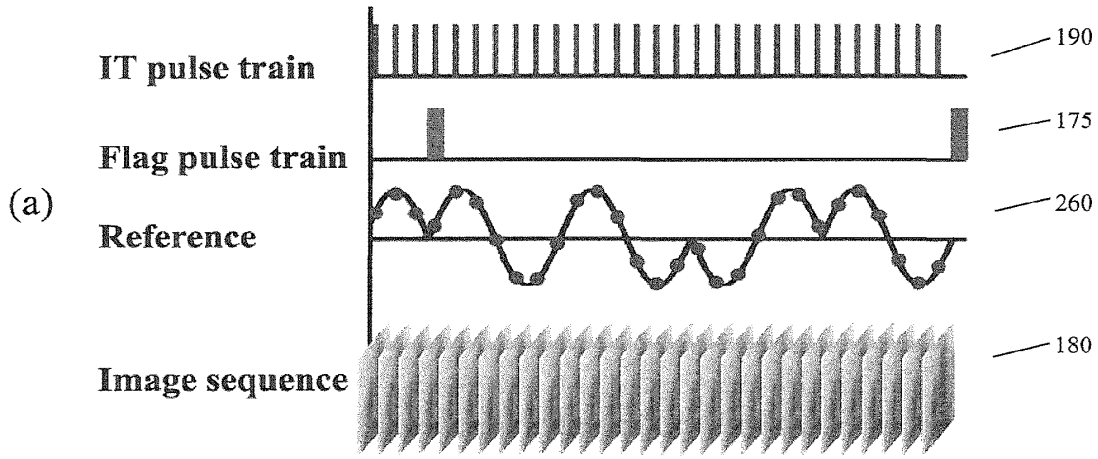
IT pulse train
190
Flag pulse train
175
In-phase Ref.
160
f(t) x sin(t)
$\sum_1$
S^0
200
Image sequence
f(t)
180
f(t) x -cos(t)
$\sum_2$
S^{90}
210
Quadrature Ref.
165

Figure 2

(a)
IT pulse train
190
Flag pulse train
175
Reference
250
Image sequence
180

(b)
Cross-correlation Signal
365
335
370
τ
300
310
325
Complex conjugate
330
Ref(t)
FFT
Z*
IFFT
Real
Imag.
τ_P
τ'_P
350
360
Phase Signal
HT
FFT
Z*
IFFT
Real
Imag.
Real
r
Imag
θ
τ
S(t)
FFT
345
355
305
320
315
340

Figure 3


(a)
IT pulse train
Flag pulse train
Reference
Image sequence
190
175
260
180

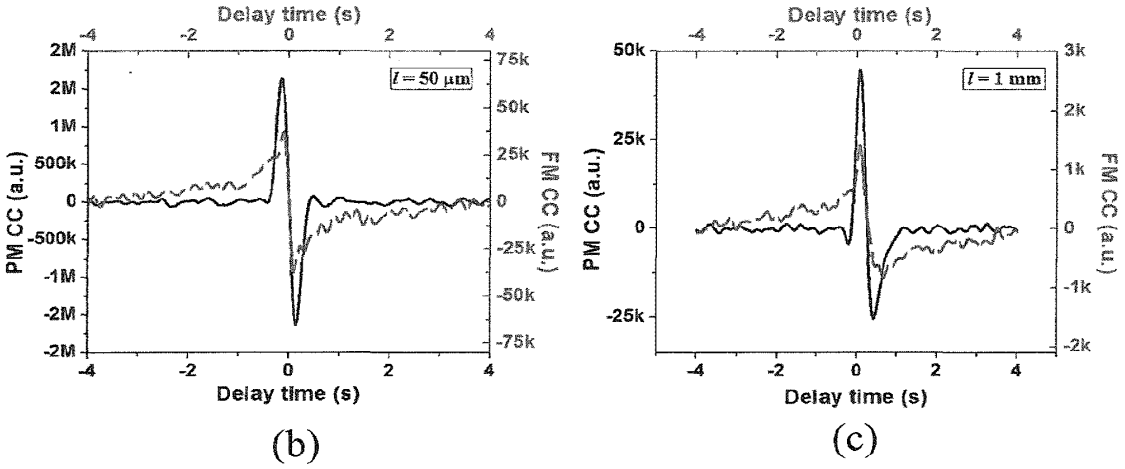

Delay time (s)
PM CC (a.u.)
FM CC (a.u.)
l = 50 μm
(b)
l = 1 mm
(c)

Figure 4

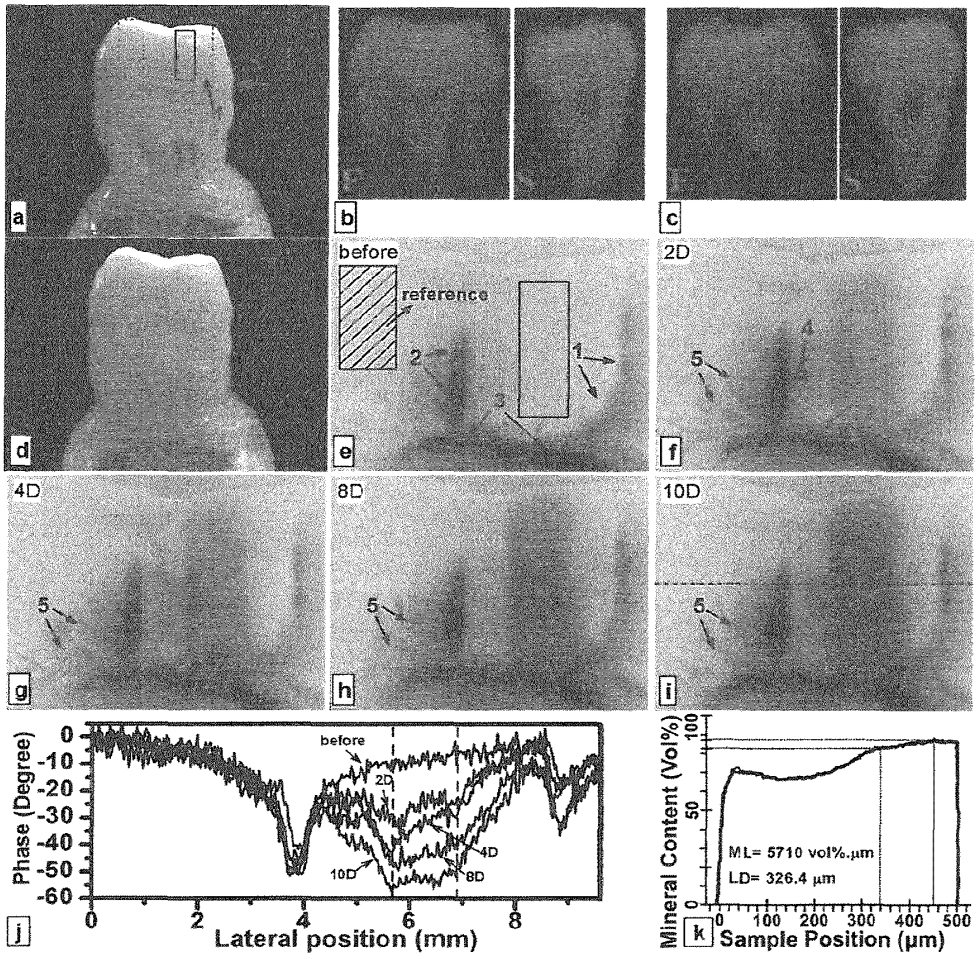

a
b
c
d
before
reference
2
1
3
e
2D
4
5
f
4D
5
g
8D
5
h
10D
5
i
Phase (Degree)
0
-10
-20
-30
-40
-50
-60
before
2D
4D
8D
10D
0
2
4
6
8
Lateral position (mm)
j
Mineral Content (Vol%)
100
50
0
ML= 5710 vol%.µm
LD= 326.4 µm
0
100
200
300
400
500
Sample Position (µm)
k

Figure 5

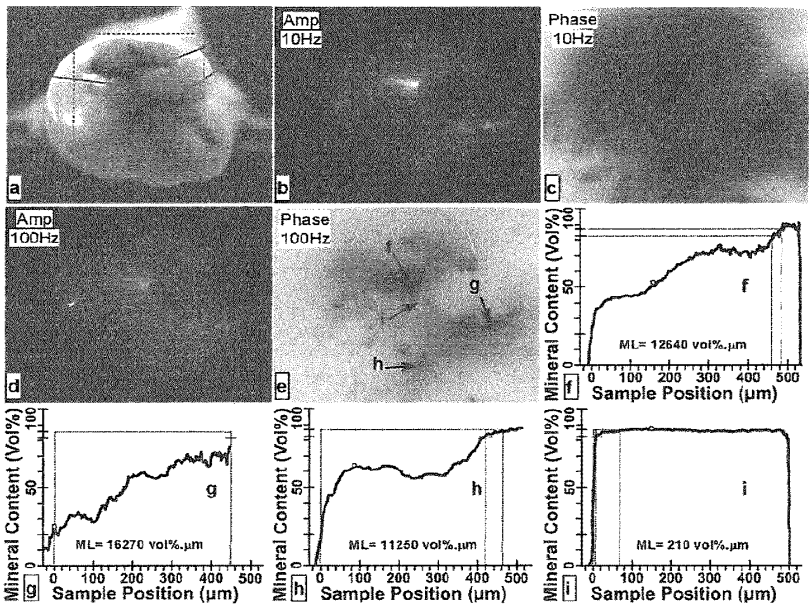


Figure 6

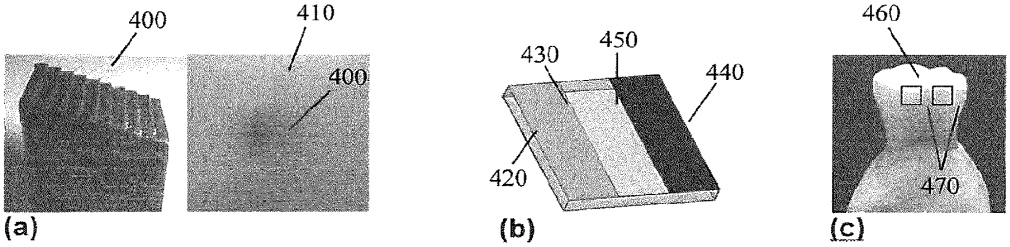


Figure 7

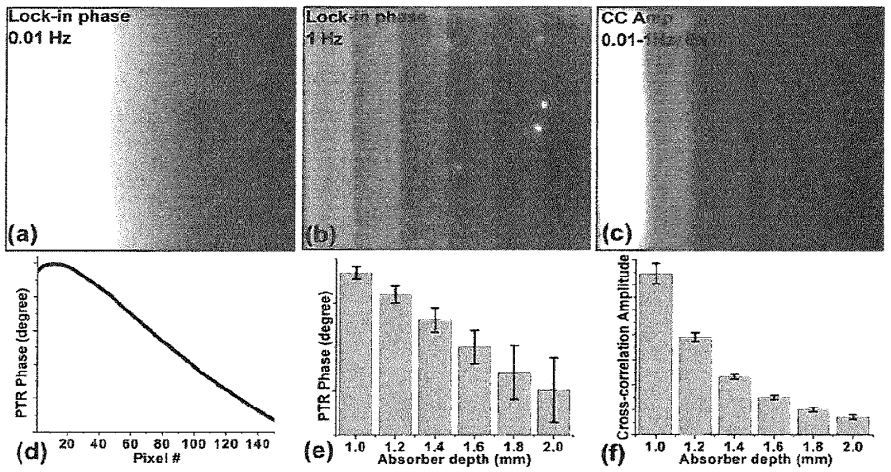


Figure 8

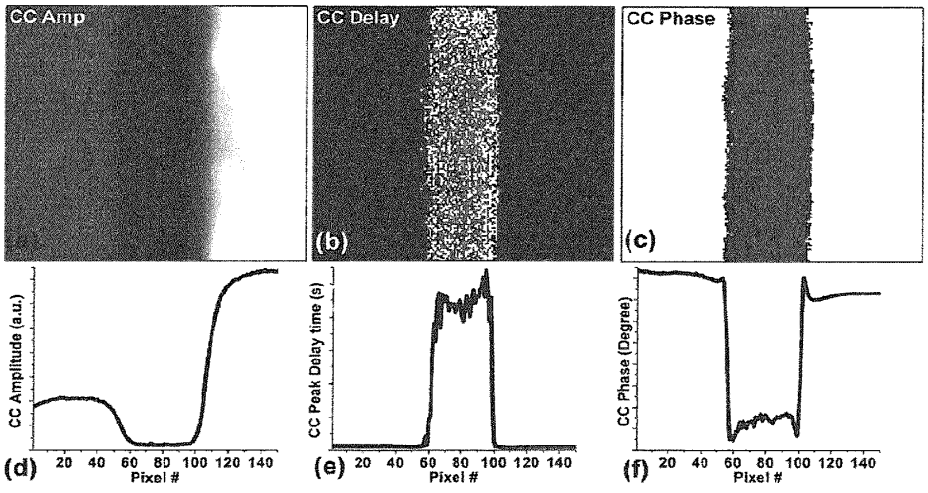


Figure 9

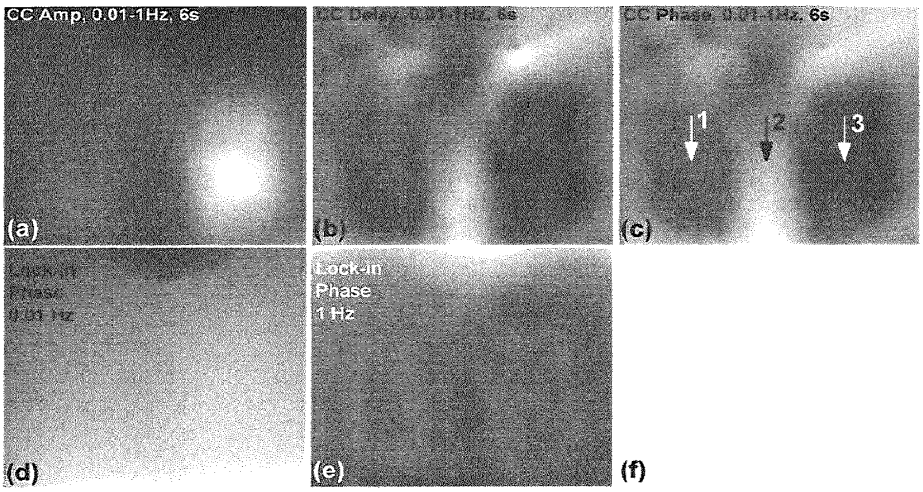


Figure 10

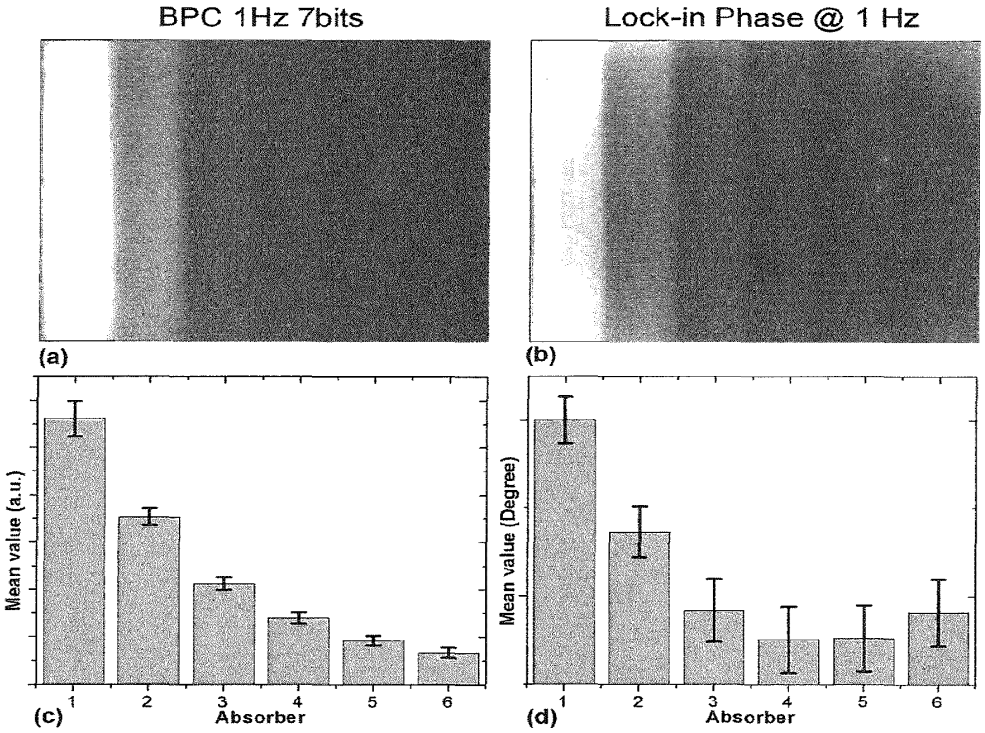

BPC 1Hz 7bits
Lock-in Phase @ 1 Hz
(a)
(b)
Mean value (a.u.)
Mean value (Degree)
1
2
3
4
5
6
Absorber
(c)
(d)

Figure 11

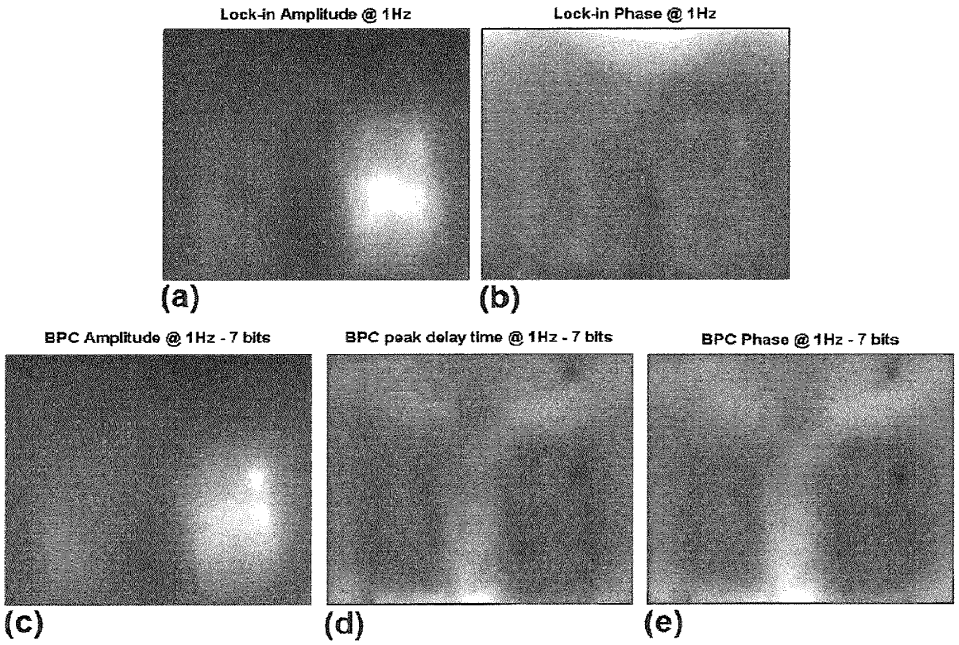

Lock-in Amplitude @ 1Hz
Lock-in Phase @ 1Hz
(a)
(b)
BPC Amplitude @ 1Hz - 7 bits
BPC peak delay time @ 1Hz - 7 bits
BPC Phase @ 1Hz - 7 bits
(c)
(d)
(e)

Figure 12

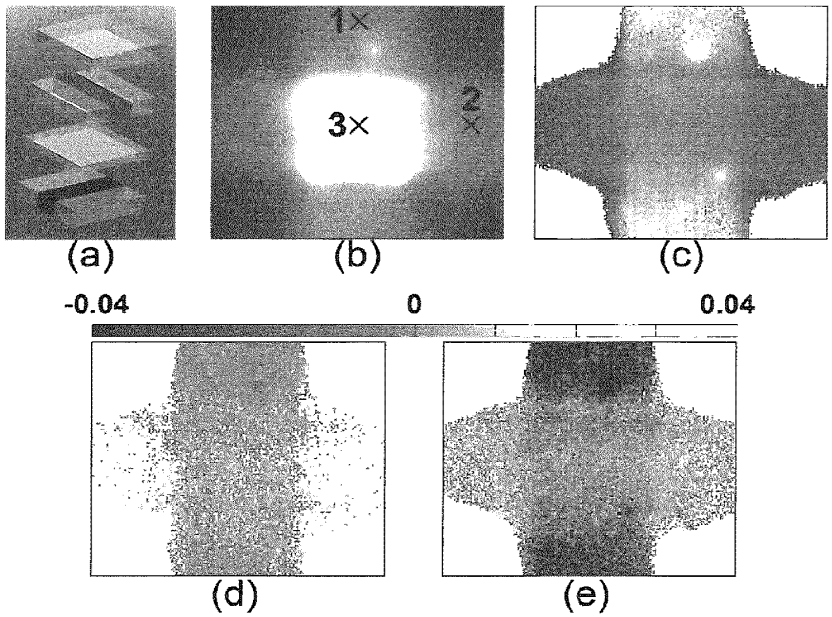


Figure 13

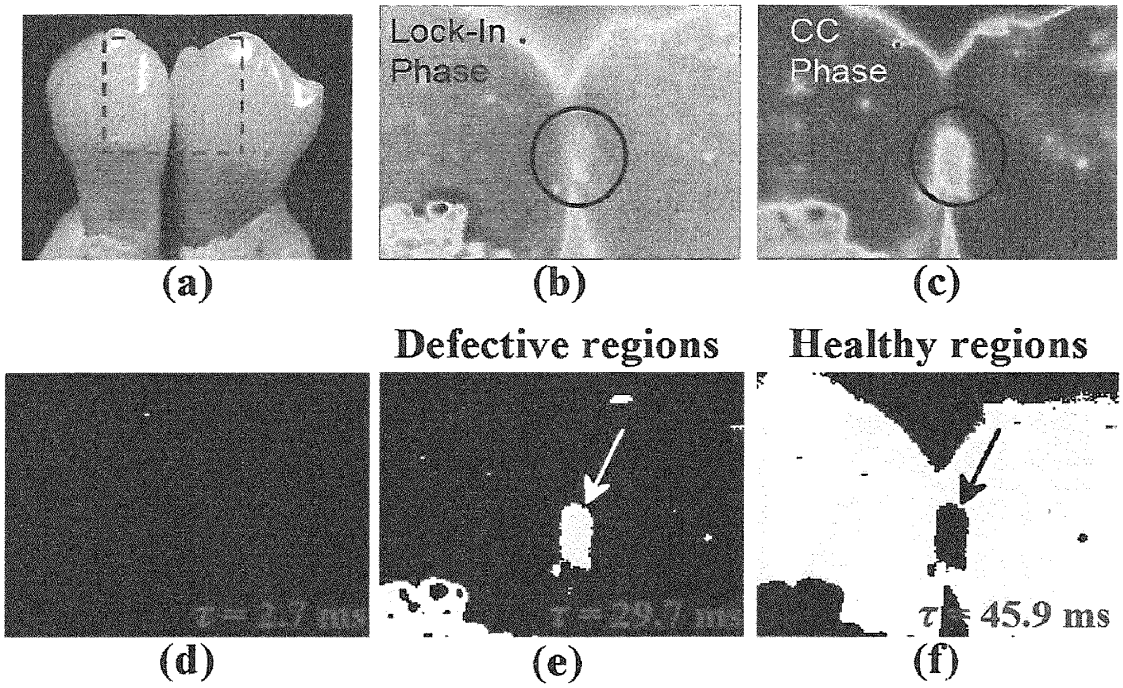

Lock-In
Phase
CC
Phase
(a)
(b)
(c)
Defective regions
Healthy regions
τ = 2.7 ms
τ = 29.7 ms
τ = 45.9 ms
(d)
(e)
(f)

Figure 14

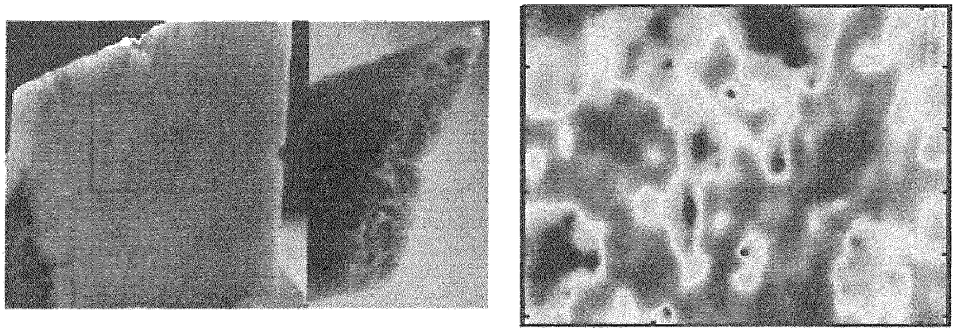


Figure 15

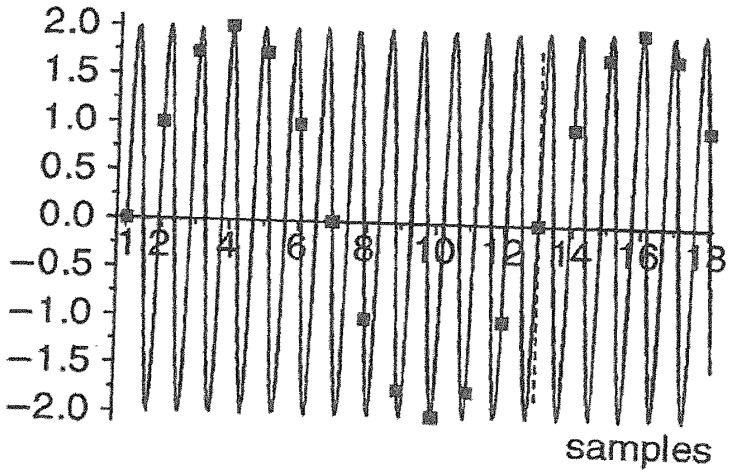


Figure 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2012/050035

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***G01N 21/63*** (2006.01) , ***A61B 6/14*** (2006.01) , ***H04N 5/33*** (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)

IPC: ***G01N 21/63*** (2006.01) , ***A61B 6/14*** (2006.01) , ***H04N 5/33*** (2006.01) (in combination with 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)

Total Patent (keywords thermophotonic, thermographic, imaging, reference, waveform, dynamic averaging)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO2010065052A1, Herman et al. 10 June 2010 (10-06-2010) (See whole document)	1-35, 37-56
A	EP1258136A2, Shepard et al. 20 November 2002 (20-11-2002) (See whole document)	1-35, 37-56
A	US7551769B2, Enachescu et al. 23 June 2009 (23-06-2009) (See whole document)	1-35, 37-56
A	WO2009123799A1, Ringermacher et al.08 October 2009 (08-10-2009) (See whole document)	1-35, 37-56
A	WO2011137264A1, Walther et al. 03 November 2011 (03-11-2011) (See whole document)	1-35, 37-56

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 June 2012 (13-06-2012)	14 June 2012 (14-06-2012)

Name and mailing address of the ISA/CA	Authorized officer
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	David E. Green (819) 994-8213

IPR2025-01250 Page 00911

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2012/050035

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. [X] Claim Nos. : 36
because they relate to subject matter not required to be searched by this Authority, namely :

Claim 36 relates to a method of medical treatment

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.

IPR2025-01250 Page 00912

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2012/050035

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO2010065052A1	10 June 2010 (10-06-2010)	US2011230942A1	22 September 2011 (22-09-2011)
EP1258136A2	20 November 2002 (20-11-2002)	AT423966T	15 March 2009 (15-03-2009)
		AU1813201A	12 June 2001 (12-06-2001)
		DE60041661D1	09 April 2009 (09-04-2009)
		EP1258136A4	20 September 2006 (20-09-2006)
		EP1258136B1	25 February 2009 (25-02-2009)
		EP1258136B8	22 April 2009 (22-04-2009)
		JP2004530309A	30 September 2004 (30-09-2004)
		JP4467862B2	26 May 2010 (26-05-2010)
		US2002044679A1	18 April 2002 (18-04-2002)
		US6516084B2	04 February 2003 (04-02-2003)
		US2002172410A1	21 November 2002 (21-11-2002)
		US6751342B2	15 June 2004 (15-06-2004)
		US2005008215A1	13 January 2005 (13-01-2005)
		US7724925B2	25 May 2010 (25-05-2010)
		WO0141421A2	07 June 2001 (07-06-2001)
		WO0141421A3	06 December 2001 (06-12-2001)
		WO02089042A1	07 November 2002 (07-11-2002)
US7551769B2	23 June 2009 (23-06-2009)	CN1620603A	25 May 2005 (25-05-2005)
		CN100480693C	22 April 2009 (22-04-2009)
		JP2006505764A	16 February 2006 (16-02-2006)
		JP2009008687A	15 January 2009 (15-01-2009)
		US2003137318A1	24 July 2003 (24-07-2003)
		US6840666B2	11 January 2005 (11-01-2005)
		US2003222220A1	04 December 2003 (04-12-2003)
		US7149343B2	12 December 2006 (12-12-2006)
		US2007036420A1	15 February 2007 (15-02-2007)
		WO03062809A1	31 July 2003 (31-07-2003)
WO2009123799A1	08 October 2009 (08-10-2009)	CA2718762A1	08 October 2009 (08-10-2009)
		DE112009000634T5	10 February 2011 (10-02-2011)
		GB201016950D0	24 November 2010 (24-11-2010)
		GB2471047A	15 December 2010 (15-12-2010)
		GB2471047B	30 May 2012 (30-05-2012)
		JP2011516837A	26 May 2011 (26-05-2011)
		US2009245321A1	01 October 2009 (01-10-2009)
WO2011137264A1	03 November 2011 (03-11-2011)	None	

IPR2025-01250 Page 00913

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

109543 7590 01/10/2017
Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	10/06/2015	Mohammed N. Islam	OMNI 0105 PUSP1	7496

TITLE OF INVENTION: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	04/10/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
FEIN, ABRA S	2884	250-338400

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Brooks Kushman P.C.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Omni Medsci, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Ann Arbor, MI

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 02-3978 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /David S. Bir/ Date April 7, 2017

Typed or printed name David S. Bir Registration No. 38,383

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	14875709
Filing Date:	06-Oct-2015
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Filer:	David S. Bir/Pamela Demos
Attorney Docket Number:	OMNI 0105 PUSP1

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**480**

Electronic Acknowledgement Receipt	
EFS ID:	28859984
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	09-APR-2017
Filing Date:	06-OCT-2015
Time Stamp:	23:02:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$480
RAM confirmation Number	041017INTEFSW00007492023978
Deposit Account	023978
Authorized User	David Bir
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Issue_Fee_Transmittal.pdf	369406 eac9d4486d55698cd5725a9ce3f3f68f455b039b	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30586 7e9c1fc0da45399d5cf60bf132021e838871a880	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	399992		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060058683	A1	2006-03-16	Chance	
	2	20160327476	A1	2016-11-10	ISLAM	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	101849821	CN	B	2013-07-04	Univ Huazhong Science Tech	See EP Search Report cited below	
	2	2012135952	WO	A1	2012-10-11	The Governing Council Of The University Of Toronto	See EP Search Report cited below	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S.F/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14875709
	Filing Date	2015-10-06
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	2884
	Examiner Name	Abra S. Fein
	Attorney Docket Number	OMNI 0105 PUSP1

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add]

NON-PATENT LITERATURE DOCUMENTS [Remove]

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Extended European Search Report for European Application No. 17156625.0 dated March 20, 2017	

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

EXAMINER SIGNATURE

Examiner Signature	/ABRA S FEIN/	Date Considered	04/14/2017

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S.F/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14875709
Filing Date	2015-10-06
First Named Inventor	Mohammed N. ISLAM
Art Unit	2884
Examiner Name	Abra S. Fein
Attorney Docket Number	OMNI 0105 PUSP1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David S. Bir/	Date (YYYY-MM-DD)	2017-03-28
Name/Print	David S. Bir	Registration Number	38383

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S.F/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S.F/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5747806		1998-05-05	Khalil	
	2	6115673		2000-09-05	Malin	
	3	6512936	B1	2003-01-28	MONFRE	
Change(s) applied to document, /S.D./ 1/24/2017	4	~~6534012~~ 6,543,012	B1	2003-04-01	VISWANATHAN	
	5	6640117		2003-10-28	Makarewicz	
	6	6788965	B2	2004-09-07	RUCHTI	
	7	6816241		2004-11-09	Grubisic	
	8	6738652	B2	2004-05-18	MATTU	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

Exs. vol. 2 of 2

Receipt date: 10/06/2015	Application Number	14875709 - GAU: 2884
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	
(Not for submission under 37 CFR 1.99)	First Named Inventor	Mohammed N. ISLAM
	Art Unit	
	Examiner Name	
	Attorney Docket Number	OMNI 0105 PUSP1

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	EP1148666	EP		2001-10-24	Grant Andrew R et al.		☐
Change(s) applied to document, /S.D./ 1/24/2017	2	~~WO01150959~~ WO0150959	WO		2001-07-19	SUHM		☐
	3	~~WO09715240~~ WO9715240	WO		1997-05-01	BRANT		☐
	4	WO97049340	WO		1997-12-31	WANG		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button **Add**

NON-PATENT LITERATURE DOCUMENTS **Remove**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Abra Fein/	Date Considered	05/13/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/875,709	05/16/2017	9651533	OMNI 0105 PUSP1	7496

109543 7590 04/26/2017

Brooks, Kushman P.C./Cheetah Omni MedSci
1000 Town Center
Twenty Second Floor
Southfield, MI 48075

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Mohammed N. Islam, Ann Arbor, MI;
OMNI MEDSCI, INC., Ann Arbor, MI;

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MOHAMMED N. ISLAM

Group Art Unit: 2884

Examiner: FEIN, ABRA S.

Serial No.: 14/875709

Filed: 10/6/2015

For: SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL

Attorney Docket No.: OMNI 0105 PUSP1

REQUEST FOR CERTIFICATE OF CORRECTION

Attention Certificate of Correction Branch
Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

It is requested that a Certificate of Correction be issued for the above-identified patent under the provisions of 37 C.F.R. § 1.322. The corrections noted are as follows:

Column 30, Line 31, Claim 9:
(Page 9, Line 1, Claim 11: Amendment dated July 6, 2016):

After "The system of claim"
Delete "89" and
Insert – 8 --.

Filed herewith is the form for Certificate of Correction (PTO/SB/44). The Commissioner is hereby authorized to charge any additional fees to our Deposit Account No. 02-3978.

Respectfully submitted,

MOHAMMED N. ISLAM

By: /David S. Bir/
David S. Bir
Reg. No. 38,383
Attorney/Agent for Applicant

Date: July 10, 2017

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.:	9,651,533
APPLICATION NO.:	14/875,709
ISSUE DATE:	May 16, 2017
INVENTOR(S):	MOHAMMED N. ISLAM (et al.)

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 30, Line 31, Claim 9:

After "The system of claim"
Delete "89" and
Insert – 8 --.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

BROOKS KUSHMAN P.C.
1000 Town Center, 22nd Floor
Southfield, MI 48075-1238

Electronic Acknowledgement Receipt

EFS ID:	29733232
Application Number:	14875709
International Application Number:	
Confirmation Number:	7496
Title of Invention:	SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL
First Named Inventor/Applicant Name:	Mohammed N. Islam
Customer Number:	109543
Filer:	David S. Bir
Filer Authorized By:	
Attorney Docket Number:	OMNI 0105 PUSP1
Receipt Date:	11-JUL-2017
Filing Date:	06-OCT-2015
Time Stamp:	14:49:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	Request_for_Certificate_of_Correction.pdf	18156 476fc9086ed5c96b4662d255de122967b7bba722	no	2

Warnings:

Information:					
2	Request for Certificate of Correction	Certificate_of_Correction.pdf	17852 4759ed4cfc0ae94754b08972511ddce66ab4387a	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	36008	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 9,651,533 B2
APPLICATION NO.	: 14/875709
DATED	: May 16, 2017
INVENTOR(S)	: Mohammed N. Islam et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 30, Line 31, Claim 9:
After "The system of claim"
Delete "89" and
Insert -- 8 --.

Signed and Sealed this
Fifteenth Day of August, 2017

Joseph Matal

Joseph Matal
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Eastern District of Texas on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
2:18-cv-134	4/6/2018	Eastern District of Texas

PLAINTIFF	DEFENDANT
Omni MedSci, Inc.	Apple Inc.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	9,651,533	5/16/2017	Omni MedSci, Inc.
2	9,757,040	9/12/2017	Omni MedSci, Inc.
3	9,861,286	1/9/2018	Omni MedSci, Inc.
4	9,885,698	2/6/2018	Omni MedSci, Inc.
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

Trials@uspto.gov
571-272-7822

Paper No. 14
Filed: October 16, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Case IPR2019-00913
Patent 9,651,533 B2

Before GRACE KARAFFA OBERMANN, JOHN F. HORVATH, and SHARON FENICK, *Administrative Patent Judges.*

HORVATH, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

A. Background

Apple Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 5, 7–10, 13, and 15–17 ("the challenged claims") of U.S. Patent No. 9,651,533 B2 (Ex. 1001, "the '533 patent"). Paper 1 ("Pet."), 4. Omni MedSci Inc. ("Patent Owner"), filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We have authority under 35 U.S.C. § 314. Upon consideration of the Petition and Preliminary Response we are persuaded that Petitioner has failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '533 patent. Accordingly, we deny institution of *inter partes* review.

B. Related Matters

Petitioner and Patent Owner identify the following as matters that can affect or be affected by this proceeding: pending U.S. Patent Application Nos. 10/188,299, 10/172,523, 15/594,053, 16/015,737, and 16/241,628; *Apple Inc. v. Omni MedSci Inc.*, IPR2019-00916 (PTAB); and *Omni MedSci Inc. v. Apple Inc.*, 2-18-cv-00134-RWD (E.D.Tex).[1] *See* Pet. xi; Paper 5, 1–2.

[1] This case has been transferred to the Northern District of California, however, has yet to be assigned a case number by that Court. *See* Paper 9, 1; Paper 11, 1; Ex. 1058, 9.

C. Evidence Relied Upon[2]

Reference		Publication Date	Exhibit
Valencell 093[3]	U.S. 2012/0197093 A1	Aug. 2, 2012	1005
Valencell 099[4]	U.S. 2010/0217099 A1	Aug. 26, 2010	1006
Mannheimer	U.S. 5,746,206	May 5, 1998	1008
Carlson	U.S. 2005/0049468 A1	Mar. 3, 2005	1009

D. Asserted Grounds of Unpatentability[5]

Claims Challenged	Basis	References
5, 7–10, 13, and 15–17	§ 103(a)	Valencell 093 and Valencell 099
5, 7–10, 13, and 15–17	§ 103(a)	Valencell 093, Valencell 099, and Carlson
8, 9, 16, and 17	§ 103(a)	Valencell 093, Valencell 099, and Mannheimer

[2] Petitioner also relies upon the Declaration of Brian Anthony, Ph.D., (Ex. 1003).

[3] Valencell is not listed as an inventor on the '093 patent application publication. Nonetheless, we follow Petitioner's convention and name the reference "Valencell 093."

[4] Valencell is not listed as an inventor on the '099 patent application publication. Nonetheless, we follow Petitioner's convention and name the reference "Valencell 099."

[5] Petitioner identifies the third ground as obviousness of claims 8, 9, 16, and 17 over Valencell 093 and Valencell 099 in view of Mannheimer, with or without Carlson. *See* Pet. 4. We treat this as two separate grounds: (1) obviousness over Valencell 093, Valencell 099, and Mannheimer; and (2) obviousness over Valencell 093, Valencell 099, Carlson, and Mannheimer.

Claims Challenged	Basis	References
8, 9, 16, and 17	§ 103(a)	Valencell 093, Valencell 099, Carlson, and Mannheimer

II. ANALYSIS

A. The '533 Patent

The '533 patent is directed toward a physiological measurement system. The system is depicted in Figure 24 of the '533 patent, which is reproduced below.

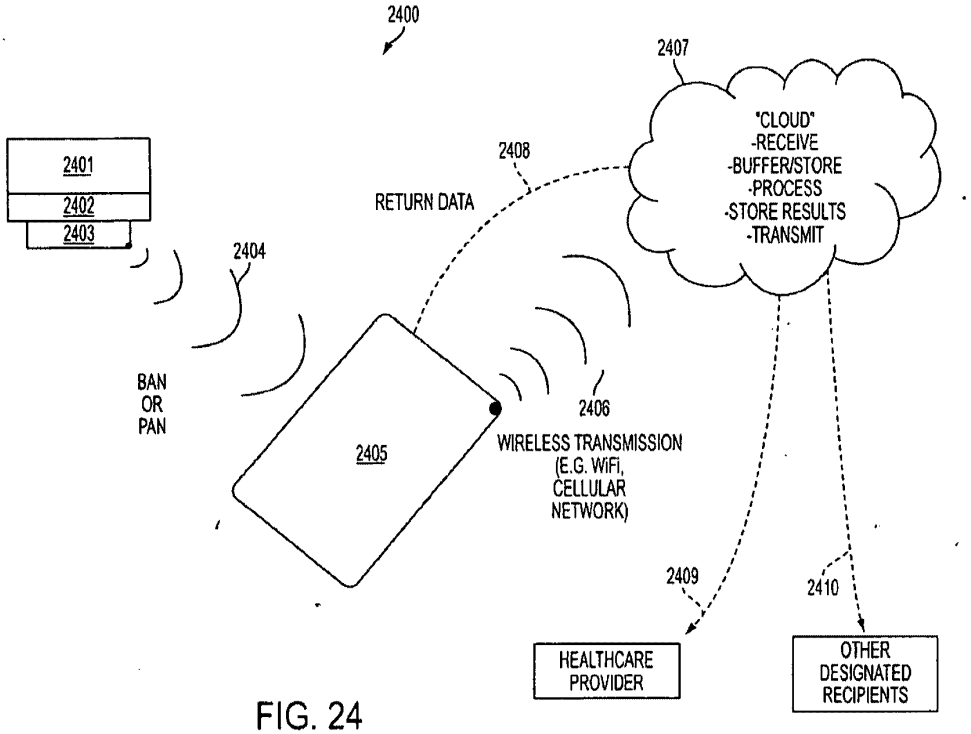


FIG. 24

Figure 24 is a schematic illustration of a physiological measurement system. Ex. 1001, 7:7–10. The system includes wearable measurement device 2401, personal device 2405, and cloud based server 2407. *Id.* at 26:49–27:20.

The "wearable measurement device [is] for measuring one or more physiological parameters." *Id.* at 5:35–37. A schematic illustration of such

a measurement device is shown in Figure 18 of the '533 patent, which is reproduced below.

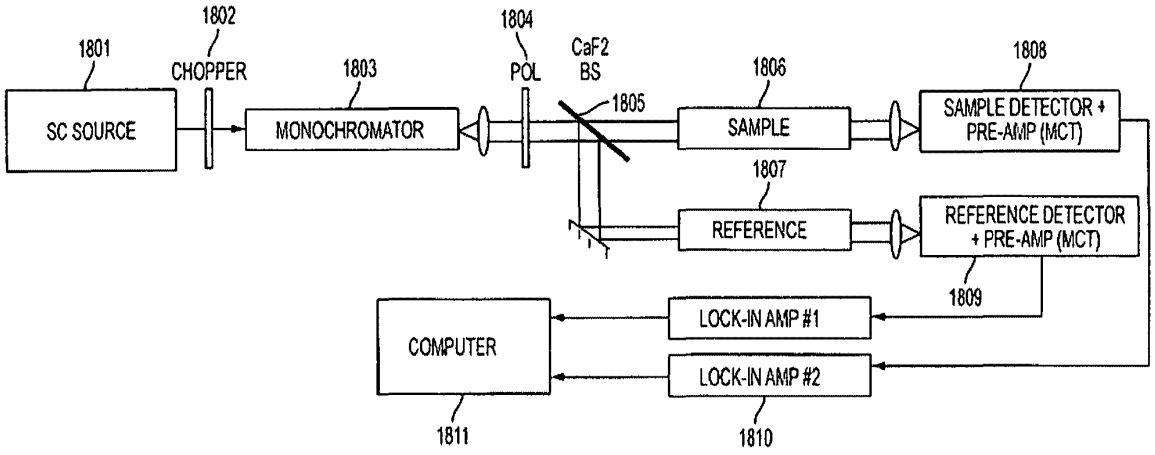


FIG. 18

Figure 18 is a schematic diagram of a device for measuring physiological parameters that may be used to "subtract out (or at least minimize the adverse effects of) light source fluctuations." *Id.* at 18:43–46.

Wearable measurement device 2401 includes light source 1801 made from a plurality of light emitting diodes that generate an output optical beam at one or more optical wavelengths, wherein at least one of the optical wavelengths is between 700 and 2500 nanometers. *Id.* at 5:37–43, 18:46–48. The light source can increase a signal-to-noise ratio by increasing either the LED intensity or pulse rate. *Id.* at 5:43–47. Wearable measurement device 2401 also includes a plurality of lenses that receive a portion of the output optical beam from the light source and deliver an analysis beam to a sample. *Id.* at 5:47–50. Lastly, wearable measurement device 2401 includes a receiver that receives at least a portion of the analysis beam that has been

reflected from or transmitted through the sample, and processes that signal to generate an output signal. *Id.* at 5:51–54.

The physiological measurement system also includes personal device 2405 having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen. *Id.* at 5:54–59, 27:3–7. Personal device 2405 receives and processes at least a portion of the output signal generated by wearable measurement device 2401, and stores and displays the processed output signal. *Id.* at 5:59–61, 27:10–12. Personal device 2405 also transmits at least a portion of the processed output signal over a wireless transmission link to a remote device, such as an internet or "cloud" based server. *Id.* at 5:61–63, 26:30–34, 27:12–15. Personal device 2405 can be "a smart phone, tablet cell phone, PDA, or computer," or some "other microprocessor-based device." *Id.* at 26:37–40, 26:49–55.

The physiological measurement system also includes remote device 2407 that receives the at least a portion of the processed output signal transmitted by personal device 2405 as an output status. *Id.* at 5:63–66, 26:30–42, 27:12–15. Remote device 2407 processes the output status to generate and store processed data, and stores a history of the output status over a period of time. *Id.* at 5:66–6:1–3, 27:21–29, 27:34–37.

B. Illustrative Claim

Claim 13 of the '533 patent is an independent and representative claim, and is reproduced below.

> 13. A measurement system comprising:
>
> a wearable measurement device for measuring one or more physiological parameters, including a light

source comprising a plurality of semiconductor sources that are light emitting diodes [LEDs], the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,

the light source configured to increase signal-to-noise ratio [SNR] by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;

the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample;

the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the wearable measurement device receiver is configured to be synchronized to the light source;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and

> a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data, and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

Ex. 1001, 30:46–31:20.

Claim 5 is an independent claim that recites a measurement system that is substantially similar to the measurement system recited in claim 13, but does not require the light source, plurality of lenses, and receiver to be components of a wearable measurement device. *Compare id.* at 29:43–30:10, *with id.* at 30:46–31:20. Claims 7–10 depend from claim 5, and claims 15–17 depend from claim 13. *Id.* at 30:15–37, 32:1–18.

C. Level of Ordinary Skill in the Art

Petitioner, relying on the testimony of Dr. Anthony, identifies a person of ordinary skill in the art ("POSITA") as someone who "would have [had] a good working knowledge of optical sensing techniques and their applications, and familiarity with optical system design and signal processing techniques." Pet. 17; Ex. 1003 ¶ 35. Such a person, according to Petitioner, would have obtained such knowledge through "an undergraduate education in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with relevant experience in studying or developing physiological monitoring devices . . . in industry or academia." Pet. 17–18. Patent Owner does not offer an opinion on Petitioner's definition, either agreeing or disagreeing, and does not offer a counter

definition of a person of ordinary skill in the art.

On this record, we find Petitioner's definition to be consistent with the problems and solutions disclosed in the patent and prior art of record. *See, e.g., In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Accordingly, we accept that definition for purposes of this Decision.

D. Claim Construction

In *inter partes* reviews, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Only claim terms which are in controversy need to be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Petitioner requests construction of the terms "beam," "plurality of lenses," and "pulse rate." Pet. 20–22. For the reasons discussed below, construction of these terms is not needed to resolve the fundamental controversy between the parties, i.e., whether Petitioner has demonstrated a reasonable likelihood of showing the unpatentability of claims 5, 7–10, 13, and 15–17. *See Nidec,* 868 F.3d at 1017.

1. Light source

Neither party requests construction of "a light source comprising a plurality of semiconductor sources that are light emitting diodes. . . configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources," recited in

independent claims 5 and 13. A construction of the term is necessary, however, to resolve the parties' dispute about whether Valencell 093 discloses such a light source.

The Specification provides scant support for the meaning of "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by increasing a light intensity from at least one of [a] plurality of semiconductor sources." This exact phrase is repeated in two passages of the Specification, without further explanation of its meaning. *See* Ex. 1001, 5:10–14, 5:43–47.[6]

Patent Owner argues that, in addition to one of the passages cited above, the '533 patent supports an LED based light source increasing signal-to-noise by increasing LED light intensity. Prelim. Resp. 20 (citing Ex. 1001, 4:15–17). The cited passage discloses "[m]ore light intensity can help to increase the signal levels, and, hence, the signal-to-noise ratio." Ex. 1001, 4:15–17. However, this disclosure appears in the context of discussing the difficulties encountered detecting certain signals "when a weak light source is used, such as a lamp." *Id.* at 4:9–15.

Elsewhere, the '533 patent reinforces the notion of selecting a high intensity LED as a light source over a weak intensity lamp. *See id.* at 8:17–24 ("[I]n hyper-spectral imaging a lamp may be used as the light source. However . . . . it would be advantageous to have a broadband light source

[6] We note that these phrases were added to the Specification by an amendment dated July 6, 2016, the same date then pending claims 5 and 14 (which issued as claims 5 and 13) were amended to contain the same limitation. *See* Ex. 1002, 495–496, 500–503. The applicant, in its remarks accompanying these amendments, did not indicate where they were supported by the Specification as originally filed. *See id.* at 505–507.

covering the SWIR [short wave infrared] that may be used in place of a lamp."); 10:6–8 ("[U]sing a non-lamp based light source could lead to contact-free control and analysis of drugs."), 19:36–46 ("Different light sources may be selected for the SWIR based on the needs of the application. Some of the features for selecting a particular light source include power or intensity. . . . Depending on the application, lamps [or] light emitting diodes (LEDs) . . . may be advantageously used."), 19:50–66 ("Lamps may be used if low power or intensity of light is required in the SWIR. . . . LED's can be used that have a higher power level in the SWIR wavelength range."). These passages, which disclose the advantages of selecting a high intensity LED light source over a low intensity lamp, do not disclose increasing the intensity of at least one LED in a multi-LED based light source. Therefore, they are not relevant to the construction of the disputed claim term, which requires "a light source comprising a plurality of semiconductor sources that are light emitting diodes." *Id.* at 30:48–50.

Other passages of the '533 patent disclose increasing the light intensity of a laser diode (LD) based light source, rather than an LED based light source, by combining the light output of the LDs. For example, the '533 patent discloses a "block diagram 1900 with building blocks for constructing the high power LDs" using "one or more diode bar stacks 1901," each of which may be "an array of several single emitter LDs." *Id.* at 20:51–55, Fig. 19. The brightness or intensity of this LD based light source "may be increased by spatially combining the beams from multiple stacks 1903." *Id.* at 20:59–60. This allows the power or intensity of the light source to be "increase[d] in multiples depending on the number of [laser] diodes multiplexed." *Id.* at 21:14–17. These passages are also not relevant

to the construction of the disputed claim term, which requires a "light source comprising a plurality of semiconductor sources that are light emitting diodes," and "increasing a light intensity from at least one of the plurality of semiconductor sources," rather than by increasing light intensity by combining the light from a plurality of semiconductor sources. *Id.* at 30:48–50, 30:56–58.

Given the scant disclosures in the Specification discussed above, for the purposes of this Decision, we construe "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by increasing a light intensity from at least one of [a] plurality of semiconductor sources" to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes has a variable intensity that can be increased in order to increase a signal-to-noise ratio." This construction is supported by the Specification at column 5, lines 10 through 14, and lines 43 through 47, and is consistent with the plain words used in the claim term at issue.[7]

E. Overview of the Prior Art

1. Valencell 093

Valencell 093 discloses a wearable monitoring apparatus, such as an earpiece or earbud, having a sensor module that "includes an energy emitter, a detector, a filter, and at least one processor." Ex. 1005 ¶ 6. "The energy emitter directs energy (e.g., optical energy . . .) at a target region of the subject and the detector detects an energy response signal" indicative of "a

[7] *See* note 6, *supra.*

physiological condition of the subject." *Id.* The "processor controls operations of the energy emitter, detector, and/or filter." *Id.* ¶ 7.

A system level diagram of Valencell 093's wearable monitoring apparatus is shown in Figure 1, reproduced below.

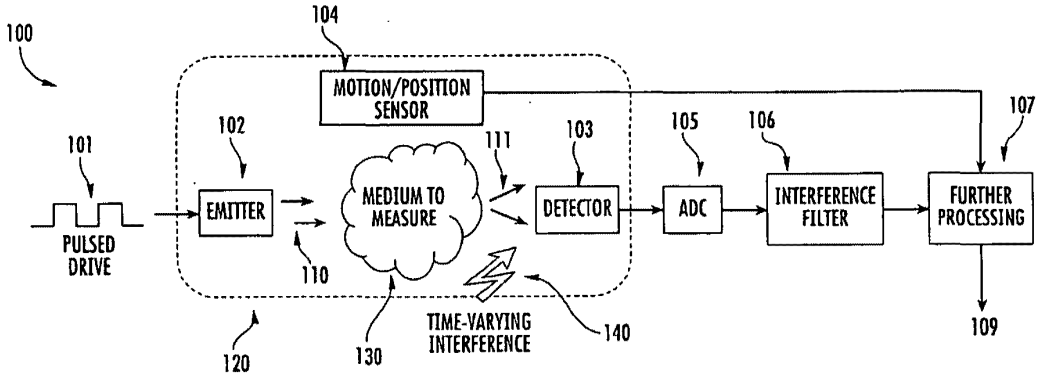


FIG. 1

Figure 1 of Valencell 093 is a schematic illustration of a "filtering apparatus/ method 100." *Id.* ¶ 107. "A pulsed driving circuit 101 is used to drive at least one energy emitter 102 at one or more pulsed frequencies to interrogate at least one target region of . . . medium 130 with . . . pulsed energy 110." *Id.* Energy emitter 102 can include "one or more optical sources," such as LEDs, "emitting one or more optical wavelengths," such as "UV, visible, and IR wavelengths." *Id.* ¶¶ 9, 109.

The optical energy reaching medium 130 "generate[s] at least one energy response signal 111, such as an optical scatter signal 111." *Id.* ¶ 107. Optical scatter signal 111 "is detected by at least one detector 103, configured to detect energy . . . in the form of optical energy scattered from the medium 130." *Id.* The output of detector 103 is "sent to at least one analog-to-digital converter (ADC) 105 and the digitized output may be sent

to at least one interference filter 106 . . . to remove the effects of time-varying environmental interference 140." *Id.*

Pulsed driving circuit 101 modulates the intensity of pulsed optical energy 110 "such that the intensity is time-varying with at least two states, preferably an on state and an off state." *Id.* ¶ 108. "A first optical interaction response is obtained by at least one detector 103 . . . when the pulsed optical energy 110 is in the on state," and a "second energy response . . . is obtained by the optical detector 103 when the pulsed optical energy 110 is in the off state." *Id.* "The first and second energy response signals . . . are processed via an interference filter 106 to produce a processed energy response signal." *Id.* Interference filter 106 "removes time-varying environmental interference caused by an interferant, such as sunlight, ambient light, airflow, temperature, etc." *Id.* "The output of the interference filter 106 is then processed by a signal extraction filter 107 to accurately extract at least one physiological property of the subject." *Id.*

2. Valencell 099

Valencell 099 discloses "a method of monitoring the health of one or more subjects [by] receiving physiological . . . information from each subject via respective portable monitoring devices." Ex. 1006 ¶ 14. Each monitoring device contains a physiological sensor "to detect and/or measure physiological information from the subject" that may be "analyzed locally via the monitoring device or may be transmitted to a location geographically remote from the subject for analysis." *Id.* The monitoring device may be a "headset, and earbud of a headset, or another portable device." *Id.* ¶ 7. The monitoring device can "transmit information wirelessly to a recording device, such as . . . a cell phone, a personal digital assistant (PDA), and/or a

computer" that is "capable of processing and organizing the data into meaningful displays." *Id.* ¶ 18. This allows a user to "monitor heath . . . data in real-time, and [to] access records of collected data throughout the day, week, month, etc., by observing charts and data through an audio-visual display." *Id.*

Valencell 099's health monitoring system is shown in Figure 2, which is reproduced below.

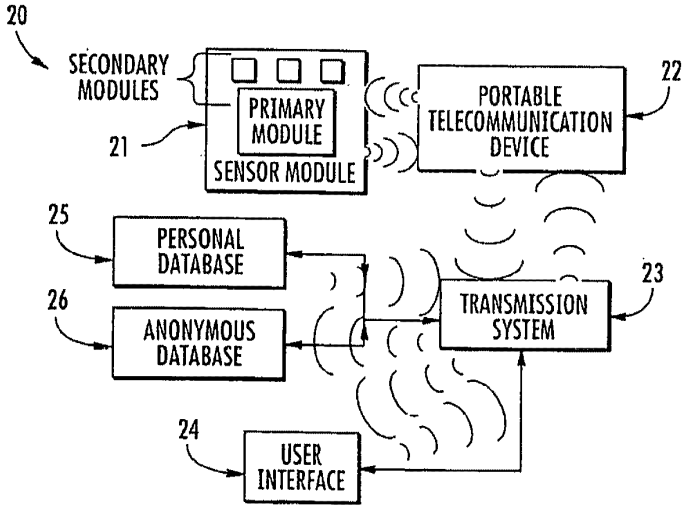


FIG. 2

Figure 2 of Valencell 099 is a "block diagram of a telemetric network for health . . . monitoring through portable telemetric monitoring devices." *Id.* ¶ 21. The network consists of portable or wearable sensor module 21, portable telecommunication device 22, transmission system 23, user interface 24, personal database 25, and anonymous database 26. *Id.* ¶ 94. "The wearable sensor module 21 communicates wirelessly with the portable telecommunication device 22," which can be "any portable device, such as a cell phone . . . PDA, laptop computer, Blackberry . . . or other portable,

telemetric device." *Id.* ¶ 96. "[T]he main purpose of the portable telecommunication device is to transmit the local wireless signal from the sensor module 21 over longer distances." *Id.* Portable telecommunication device 22 may contain user interface 24 to allow "data from the wearable sensor module 21 [to] be stored, analyzed, summarized, and displayed." *Id.* ¶ 97. Portable telecommunication device 22 also "sends/receives wireless information directly to/from a transmission system 23 for transmission to a database (such as personal database 25 and/or anonymous database 26) for storage, analysis, and retrieval of data." *Id.* ¶ 98. The database is "typically located far away from the user and telecommunication module," and information from the wearable sensor module 21 and telecommunication device 21 is "sent to [the] database through the Internet." *Id.*

3. Carlson

Carlson discloses an "optical pulsoximetry [device] used for non-invasive measurement of pulsation and oxygen saturation in arterial human or animal blood." Ex. 1009 ¶ 2. The device measures the light "absorption of reduced (Hb)—and oxidized (HbO_2) h[e]moglobin at two optical wavelengths, where the relative absorption coefficients differ significantly." *Id.* ¶ 3. Figure 2 of Carlson is reproduced below.

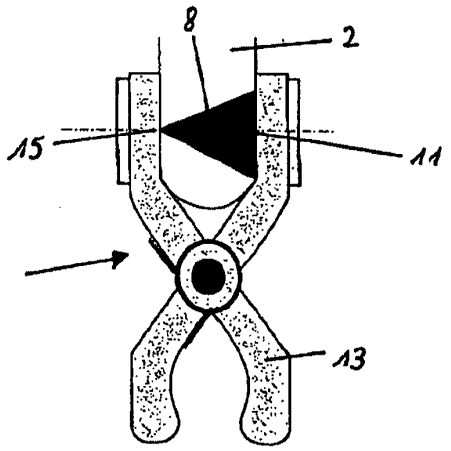


Figure 2

Figure 2 of Carlson is a schematic illustration of an ear clip sensor 1 of a pulsoximeter device. *Id.* ¶¶ 33, 49. Sensor 1 includes light source 15, which transmits light beam 8 through a patient's earlobe 2, and light detector 11 to detect the transmitted light. *Id.* ¶ 49. Light source 15 emits light at two wavelengths—660nm and 890nm—and can consist of two LEDs. *Id.* ¶ 50.

Carlson's pulsoximeter can be used to "survey the heath condition of a person or an animal [that] is mobile," and is "not restricted for use in, e.g., a hospital." *Id.* ¶ 72. Carlson teaches that "standard pulsoximeter sensors suffer from signal instability and insufficient robustness versus environmental disturbances." *Id.* ¶ 4. For example, when a pulsoximeter sensor is worn by a person driving along a tree-lined avenue, the sensor will receive sunlight "at a certain frequency," such that "every time when passing a tree, sunlight is attenuated and between the trees sunlight is influencing the measurement of the pulsoximeter sensor." *Id.* ¶ 68. To address such problems, Carlson's pulsoximeter includes "optical and/or electronic means for increasing the Signal-to-Noise ratio (S/N) . . . of a pulsoximeter sensor

for robust application of pulsoximetry in telemedicine- and near patient testing applications in rough (optical) environmental conditions." *Id.* ¶ 10. In particular, the device's LEDs emit light "not as a current or continuous light but as pulsed light." *Id.* ¶ 69. The device also uses "AC-Coupling or Lock-In Amplification (synchronous detection) . . . to temporarily modulate the amplitude of the optical radiation of . . . the LED at a carrier frequency f_0 in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range." *Id.* ¶ 20. Modulation frequency f_0 is chosen so that "it is outside the frequency spectrum of sunlight and of ambient light." *Id.* ¶ 69. This allows the pulsoximeter signals to be easily discriminated from environmental signals, such as variable amounts of sunlight and ambient light, and "increas[es] significantly the Signal-to-Noise and Signal-to-Background ratio." *Id.*

Carson further discloses the pulsoximeter sensor can be wirelessly connected to "a special unit worn by [a] person or patient," where "a signal is generated if [a] measured value is not within a predetermined range." *Id.* ¶¶ 77–78. The generated signal can be "transmitted to a respective person, to a medical doctor, to a hospital, etc." *Id.* ¶ 78. The pulsoximeter can also include a "GPS device which at any time gives the location of the person using the pulsoximetric sensor monitoring configuration." *Id.*

4. Mannheimer

Mannheimer discloses a pulse oximetry device that "non-invasively measure[s] oxygen saturation of arterial blood flow in vivo." Ex. 1008, 1:10–13. Mannheimer's device performs a "pulsed oximetry measurement [that] isolates arterial saturation levels for particular ranges of tissue layers

. . . by utilizing multiple spaced detectors and/or emitters." *Id.* at 2:1–6.

Figure 1A of Mannheimer is reproduced below.

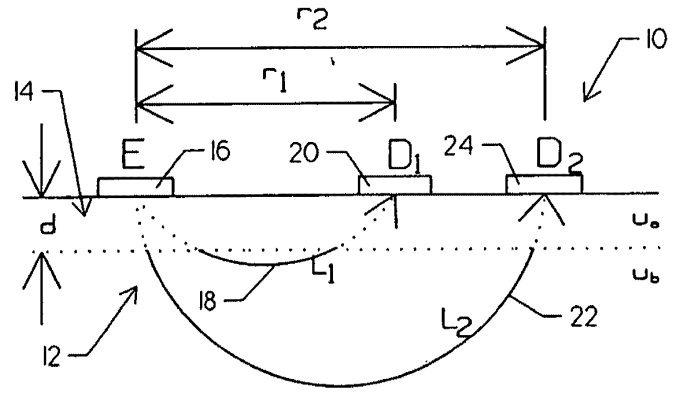


FIG. 1 A

Figure 1A of Mannheimer is a schematic diagram of a first embodiment of a pulse oximeter having one emitter 16 and two detectors 20/24. *Id.* at 2:40–42. Emitter 16 can be a single LED or multiple LEDs collocated to simulate a single point source. *Id.* at 3:13–18. Emitter 16 is separated from detector 20 by a first distance r_1, and is separated from detector 24 by a second distance r_2. *Id.* at 3:23–24. Light from emitter 16 is scattered by skin layer 14 and deeper skin layer 12, and reaches detectors 20/24 via respective paths 18/22. *Id.* at 3:18–20. Mannheimer calculates the blood oxygen concentration in skin layer 12 from the intensity of light detected at detectors 20/24 at two different times and two different wavelengths. *Id.* at 3:35–4:63.

In addition to the embodiment shown in Figure 1A, Mannheimer discloses a second embodiment of a pulse oximeter in Figure 1B, reproduced below.

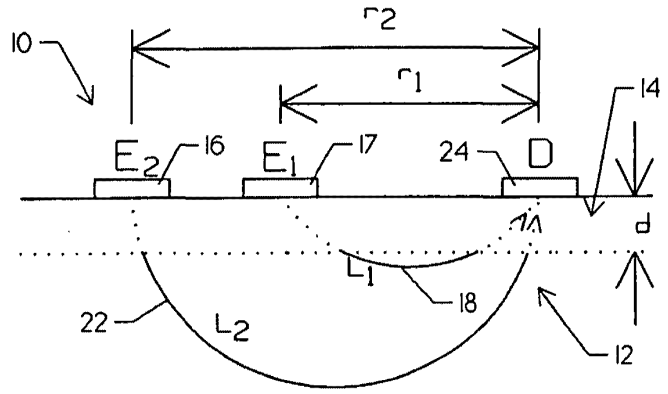


FIG. 1 B

Figure 1B of Mannheimer is a schematic diagram of a second embodiment of a pulse oximeter having two emitters 16/17 and one detector 24. *Id.* at 2:43–44, 3:37–39. As shown in Figure 1B, emitter 17 is separated from detector 24 by a first distance r_1, and emitter 16 is separated from detector 24 by a second distance r_2. Mannheimer discloses that "[t]hose of skill in the art will appreciate that the operation" of the second embodiment shown in Figure 1B "is similar to that described above" in reference to the first embodiment shown in Figure 1A. *Id.* at 5:58–62.

F. Patentability of claims 5, 7–10, 13, and 15–17

Petitioner argues claims 5, 7–10, 13, and 15–17 are unpatentable as obvious over the combination of Valencell 093 and Valencell 099, and over the combination of Valencell 093, Valencell 099, and Carlson. Pet. 23–69. Petitioner further argues claims 8, 9, 16, and 17 are unpatentable as obvious over the combination of Valencell 093, Valencell 099, and Mannheimer, and over the combination of Valencell 093, Valencell 099, Carlson, and Mannheimer. *Id.* at 69–75.

Independent claim 13 recites a measurement system comprising "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources." Ex. 1001, 30:46–58. Claim 5, the only other independent challenged claim, recites a measurement system having the same light source. *Compare id.* at 29:43–53, *with id.* at 30:46–58. As discussed above, we construe this limitation to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes (semiconductor sources) has a variable intensity that can be increased in order to increase a signal-to-noise ratio."

Petitioner argues, in each of the grounds presented, that Valencell 093 discloses a light source "configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources." *See* Pet. 36–37, 55; *id.* at 64–69 (relying on Valencell 093 to teach increasing signal-to-noise ratio by increasing the *intensity* of at least one LED, and Carlson to teach increasing signal-to-noise ratio by increasing the *pulse rate* of at least one LED); *id.* at 69–74 (relying on Valencell 093 to teach increasing signal-to-noise ratio by increasing the *intensity* of at least one LED). Specifically, Petitioner argues that Valencell 093 discloses a Bluetooth headset having a physiological sensor that includes one or more LED emitters 102. *Id.* at 33–34 (citing Ex. 1005 ¶¶ 6, 38, 104, 108, Figs. 1, 14). Petitioner further argues that LED emitters 102 are controlled by a processor such that "the *intensity* of the optical emitter 102 may be increased to increase the ratio of physiological optical scatter 111 from blood vessels with respect to unwanted sunlight." *Id.* at 36 (citing

Ex. 1005 ¶¶ 7, 107, 117; quoting *id.* ¶ 123). Therefore, Petitioner argues, Valencell 093 teaches increasing LED light intensity to increase the signal-to-noise ratio as required by claims 5 and 13. *Id.* at 36–37.

Patent Owner argues Valencell 093 fails to disclose increasing light intensity to increase the signal-to-noise ratio. Prelim. Resp. 23–25. Rather, Patent Owner argues, Valencell 093's "disclosure of increasing intensity refers to **a design process** where a human sets a fixed light intensity value, not the claimed configuration in which the light source of the sensor module 207 increases light intensity to increase the SNR." *Id.* at 24. In particular, Patent Owner argues that Valencell 093 teaches using an "interference filter 106 . . . to remove the effects of time-varying environmental interference 140," and that such filters "may reduce 'the amount of optical scatter 111 (FIG. 1) of interest from the medium 130.'" *Id.* at 23–24 (quoting Ex. 1005 ¶¶ 107, 123). Therefore, Patent Owner argues, Valencell 093 teaches "designing the emitter 102 to emit light at a higher intensity '[t]o offset this unwanted reduction in optical scatter 111.'" *Id.* at 24 (quoting Ex. 1005 ¶ 123). That is, Patent Owner argues Valencell 093 teaches selecting a filter 106 to remove sunlight, and selecting an LED of sufficient intensity to offset the attenuation of LED light intensity caused by filter 106.

We are persuaded by Patent Owner's argument. Valencell 093 discloses an embodiment in which an optical filter 710 "serve[s] as . . . an attenuation filter." Ex. 1005 ¶ 123. Regarding this embodiment, Valencell 093 explains: "Because sunlight is so powerful, it may be beneficial to reduce sunlight interference as much as possible, even if that means *also reducing the amount of optical scatter* 111 (FIG. 1) of interest from the

medium 130." *Id.* (emphasis added). Figure 1 of Valencell 093 is reproduced below.

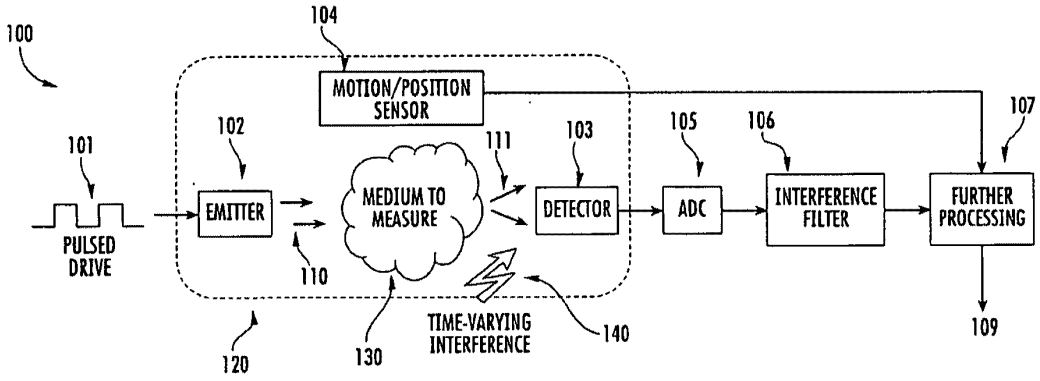


FIG. 1

Figure 1 of Valencell 093 is a schematic illustration of an interference filtering apparatus. *Id.* ¶ 53. Light produced by emitter 102 is reflected by or transmitted through medium 130, producing scattered light 111 that is detected by detector 103. *Id.* ¶ 107. Detector 103 simultaneously detects light from time-varying interference source 140, which can be sunlight. *Id.* ¶¶ 107, 110, 123.

To reduce the amount of sunlight reaching detector 103, Valencell 093 includes, in one embodiment, optical filter 710, which "serves as . . . an attenuation filter." *Id.* ¶ 123, Fig. 7. However, in addition to attenuating unwanted sunlight, filter 710 "also reduc[es] the amount of optical scatter 111" reaching detector 103. *Id.* "To offset this unwanted reduction in optical scatter 111," Valencell 093 teaches "the intensity of the optical emitter 102 may be increased." *Id.* That is, Valencell 093 teaches deploying an optical filter 710 that attenuates both unwanted sunlight 140 and optical scatter 111 from medium 130, and selecting an emitter 102 of sufficient intensity to compensate for the attenuation of optical scatter 111 by optical

filter 710. Valencell 093 fails to teach an LED-based light source configured to increase signal-to-noise by increasing LED light intensity as required by claims 5 and 13. For example, Valencell 093 fails to teach that optical filter 710 has variable attenuation, and increasing the LED intensity when the attenuation of optical filter 710 is increased.

Accordingly, for the reasons discussed above, Petitioner fails to demonstrate sufficiently that Valencell 093 teaches "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources," and, therefore, fails to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of claims 5, 7–10, 13, and 15–17 of the '533 patent.

III. CONCLUSION

For the above reasons, we determine that Petitioner fails to demonstrate a reasonable likelihood of showing claims 5, 7–10, 13, and 15–17 of the '533 patent are unpatentable on the grounds presented. Accordingly, we decline to institute *inter partes* review of these claims on these grounds.

IV. ORDER

It is ORDERED that the Petition for *inter partes* review is *denied*.

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Paper No. 16
Filed: October 18, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Case IPR2019-00916
Patent 9,651,533 B2

Before GRACE KARAFFA OBERMANN, JOHN F. HORVATH, and SHARON FENICK, *Administrative Patent Judges.*

HORVATH, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

A. Background

Apple Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 5, 7–10, 13, and 15–17 ("the challenged claims") of U.S. Patent No. 9,651,533 B2 (Ex. 1001, "the '533 patent"). Paper 1 ("Pet."), 3. Omni MedSci Inc. ("Patent Owner"), filed a Preliminary Response. Paper 10 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

Upon consideration of the Petition and Preliminary Response we are persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '533 patent. Accordingly, we institute *inter partes* review of all challenged claims on all grounds raised.

B. Related Matters

Petitioner and Patent Owner identify the following as matters that can affect or be affected by this proceeding: pending U.S. Patent Application Nos. 10/188,299, 10/172,523, 15/594,053, 16/015,737, and 16/241,628; *Apple Inc. v. Omni MedSci Inc.*, IPR2019-00913 (PTAB); and *Omni MedSci Inc. v. Apple Inc.*, 2-18-cv-00134-RWD (E.D. Tex.).[1] *See* Pet. x; Paper 7, 1–2.

[1] This case was transferred to the Northern District of California, however, that Court has not yet provided a new case number. *See* Paper 11, 1; Paper 13, 1; Ex. 1058, 9.

C. Evidence Relied Upon[2]

Reference		Date	Exhibit
Mannheimer	U.S. 5,746,206	May 5, 1998	1008
Carlson	U.S. 2005/0049468 A1	Mar. 3, 2005	1009
Lisogurski	U.S. 9,241,676 B2	May 31, 2012[3]	1011

D. Asserted Grounds of Unpatentability

Claims Challenged	Basis	References
5, 7–10, 13, and 15–17	§ 103(a)	Lisogurski and Carlson
8, 9, 16, and 17	§ 103(a)	Lisogurski, Carlson, and Mannheimer

II. ANALYSIS

A. The '533 Patent

The '533 patent was filed on October 6, 2015, and claims priority to a utility application filed on December 17, 2013 and a provisional application filed on December 31, 2012. Ex. 1001 codes (22), (60), (63), 1:10–14. The '533 patent is directed toward a wearable physiological measurement system. *Id.* code (57). The system is depicted in Figure 24 of the '533 patent, which is reproduced below.

[2] Petitioner also relies upon the Declaration of Brian Anthony, Ph.D., (Ex. 1003).

[3] Petitioner relies on the filing date of Lisogurski to establish its status as prior art. *See* Pet. 21.

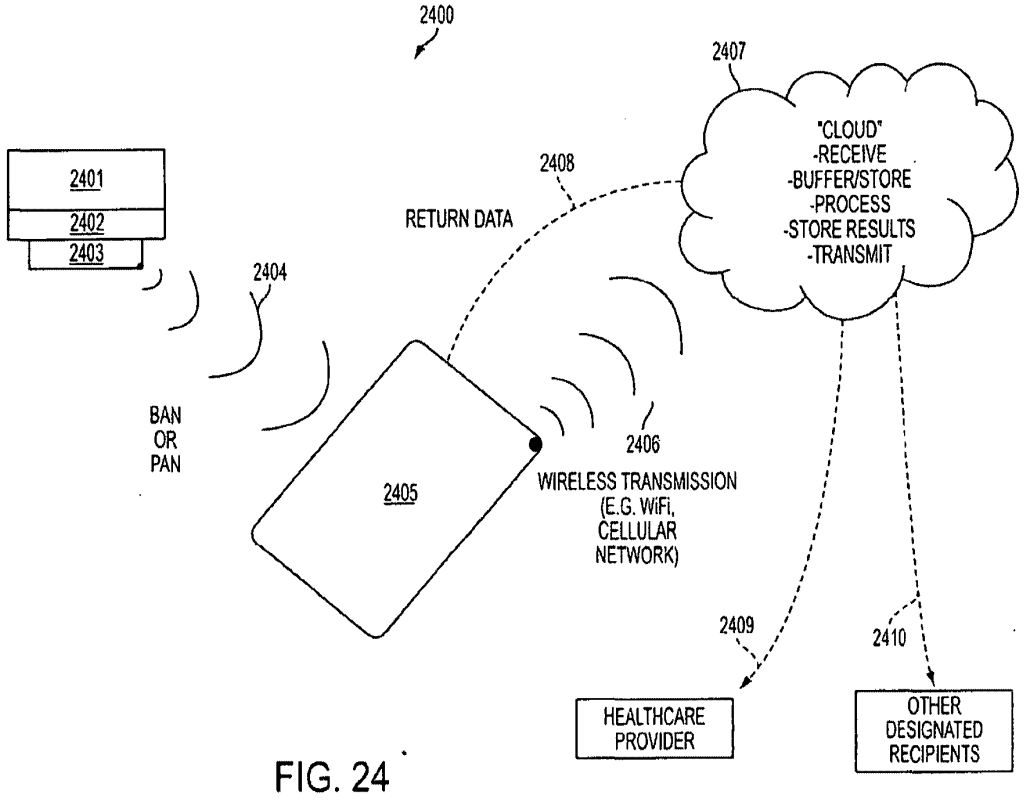


FIG. 24

Figure 24 is a schematic illustration of a physiological measurement system. *Id.* at 7:7–10. The system includes wearable measurement device 2401, personal device 2405, and cloud based server 2407. *Id.* at 26:49–27:20.

The "wearable measurement device [is] for measuring one or more physiological parameters." *Id.* at 5:35–37. A schematic illustration of such a measurement device is shown in Figure 18 of the '533 patent, which is reproduced below.

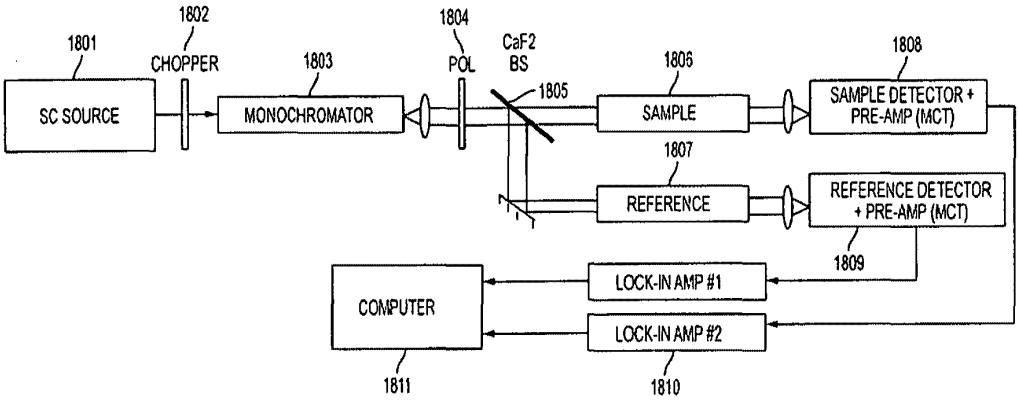


FIG. 18

Figure 18 is a schematic diagram of a device for measuring physiological parameters that may be used to "subtract out (or at least minimize the adverse effects of) light source fluctuations." *Id.* at 18:43–46.

Wearable measurement device 2401 includes light source 1801 made from a plurality of light emitting diodes that generate an output optical beam at one or more optical wavelengths, wherein at least one of the optical wavelengths is between 700 and 2500 nanometers. *Id.* at 5:37–43, 18:46–48. The light source can increase a signal-to-noise ratio by increasing either the LED intensity or pulse rate. *Id.* at 5:43–47. Wearable measurement device 2401 also includes a plurality of lenses that receive a portion of the output optical beam from the light source and deliver an analysis beam to a sample. *Id.* at 5:47–50. Lastly, wearable measurement device 2401 includes a receiver that receives at least a portion of the analysis beam that has been reflected from or transmitted through the sample, and processes that signal to generate an output signal. *Id.* at 5:51–54.

The physiological measurement system also includes personal device 2405 having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen. *Id.* at 5:54–59, 27:3–7. Personal device 2405 receives and processes at least a portion of the output signal generated by wearable measurement device 2401, and stores and displays the processed output signal. *Id.* at 5:59–61, 27:10–12. Personal device 2405 also transmits at least a portion of the processed output signal over a wireless transmission link to a remote device, such as an internet or "cloud" based server. *Id.* at 5:61–63, 26:30–34, 27:12–15. Personal device 2405 can be "a smart phone, tablet, cell phone, PDA, or computer," or some "other microprocessor-based device." *Id.* at 26:37–40, 26:49–55.

The physiological measurement system also includes remote device 2407 that receives the at least a portion of the processed output signal transmitted by personal device 2405 as an output status. *Id.* at 5:63–66, 26:30–42, 27:12–15. Remote device 2407 processes the output status to generate and store processed data, and stores a history of the output status over a period of time. *Id.* at 5:66–6:1–3, 27:21–29, 27:34–37.

B. Illustrative Claim

Claim 13 of the '533 patent is an independent and representative claim, and is reproduced below.

> 13. A measurement system comprising:
>
> a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output

optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,

the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;

the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample;

the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the wearable measurement device receiver is configured to be synchronized to the light source;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and

a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed

> output signal, to process the received output status to generate processed data and to store the processed data and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

Ex. 1001, 30:46–31:20.

Claim 5 is an independent claim that recites a measurement system that is substantially similar to the measurement system recited in claim 13, but is broader than claim 13 because it does not require the light source, plurality of lenses, and receiver to be components of a wearable measurement device, does not require the measurement of one or more physiological parameters, and does not require the remote device to be capable of storing a history of at least a portion of the received output status over a specified period of time. *Compare id.* at 29:43–30:10, *with id.* at 30:46–31:20. Claims 7–10 depend from claim 5, and claims 15–17 depend from claim 13. *Id.* at 30:15–37, 32:1–18.

C. Level of Ordinary Skill in the Art

Petitioner, relying on the testimony of Dr. Anthony, identifies a person of ordinary skill in the art ("POSITA") as someone who "would have [had] a good working knowledge of optical sensing techniques and their applications, and familiarity with optical system design and signal processing techniques." Pet. 16; Ex. 1003 ¶ 35. Such a person, according to Petitioner, would have obtained such knowledge through "an undergraduate education in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with relevant experience studying or developing physiological monitoring devices . . . in industry or academia." *Id.* Patent

Owner does not offer an opinion on Petitioner's definition, either agreeing or disagreeing, and does not offer a counter definition of a person of ordinary skill in the art.

At this stage of the proceeding, and for purposes of this Decision, we find Petitioner's definition to be consistent with the problems and solutions disclosed in the patent and prior art of record, and adopt it as our own. *See, e.g.*, *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

D. Claim Construction

In *inter partes* reviews, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Only claim terms which are in controversy need to be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Petitioner requests construction of the terms "beam," "plurality of lenses," and "pulse rate." Pet. 18–20. For the reasons discussed below, construction of these terms is not needed to resolve the fundamental controversy between the parties, i.e., whether Petitioner has demonstrated a reasonable likelihood of showing the unpatentability of claims 5, 7–10, 13, and 15–17. *See Nidec,* 868 F.3d at 1017.

1. Light source

Neither party requests construction of the term "a light source comprising a plurality of semiconductor sources that are light emitting

diodes. . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources," recited in independent claims 5 and 13. A construction of the term is necessary, however, to resolve the parties' dispute about whether Lisogurski alone or in combination with Carlson discloses such a light source.

The Specification provides scant support for the meaning of "a light source comprising a plurality of semiconductor sources that are light emitting diodes. . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources." This exact phrase is repeated in two places, without further explanation of its meaning. Ex. 1001, 5:10–15, 5:43–47.[4] There are no other disclosures in the Specification to illuminate the meaning of this term.

Given the scant disclosures in the Specification, for purposes of this Decision, we construe the term "a light source comprising a plurality of semiconductor sources that are light emitting diodes. . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources" to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes is capable of having its pulse rate increased to increase a signal-to-noise ratio." This construction is supported by the

[4] We note that these phrases were added to the Specification by an amendment dated July 6, 2016, the same date then pending claims 5 and 14 (which issued as claims 5 and 13) were amended to contain the same limitation. *See* Ex. 1002, 495–496, 500–503. The applicant, in its remarks accompanying these amendments, did not indicate where they were supported by the Specification as originally filed. *See id.* at 505-507.

Specification at column 5, lines 10 through 15, and lines 43 through 47, and is consistent with the plain words used in the claim term at issue.[5]

2. Personal device

Neither party requests construction of the "personal device" recited in independent claims 5 and 13. A construction of the term is necessary, however, to resolve the parties' dispute about whether Lisogurski discloses a personal device.

Claim 13 recites a measurement system comprising a wearable measurement device configured to "generate an output signal," a personal device "configured to receive and process at least a portion of the output signal" and to transmit "at least a portion of the processed output signal" over a wireless link, and a "remote device configured to receive over the wireless transmission link an output status comprising at least a portion of the processed output signal." Ex. 1001, 30:64–31:1, 31:4–15. The personal device includes "a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen." *Id.* at 31:4–7

The Specification discloses a "non-invasive blood constituent or analytes measurement device" that "may communicate with a smart phone, tablet, personal data assistant, computer, and/or other microprocessor-based device, which may in turn wirelessly . . . transmit some or all of the signal or processed data to the internet or cloud." *Id.* at 26:30–31, 26:37–42. Thus, the wearable measurement device can be a non-invasive blood analytes measurement device, the personal device can be a smart phone, tablet,

[5] *See* note 4, *supra*.

personal data assistant, computer, or microprocessor-based device, and the remote device can be "the cloud," which the Specification identifies as "data servers and processors in the web remotely connected." *Id.* at 26:32–33.

Accordingly, we construe the term "personal device" to include a computer or microprocessor-based device having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen.

E. Overview of the Prior Art

1. Lisogurski

Lisogurski discloses a "physiological monitoring system [that] monitor[s] one or more physiological parameters of a patient . . . using one or more physiological sensors." Ex. 1011 3:44–46. The physiological sensors may include a "pulse oximeter [that] non-invasively measures the oxygen saturation of a patient's blood." *Id.* at 3:62–64. The pulse oximeter includes "a light sensor that is placed at a sight on a patient, typically a fingertip, toe, forehead, or earlobe." *Id.* at 4:6–7. The light sensor "pass[es] light through blood perfused tissue and photoelectrically sense[s] the absorption of the light in the tissue." *Id.* at 4:8–10. The light sensor emits "one or more wavelengths [of light] that are attenuated by the blood in an amount representative of the blood constituent concentration," and may include red and infrared (IR) wavelengths of light. *Id.* at 4:42–48.

Figure 3 of Lisogurski is reproduced below.

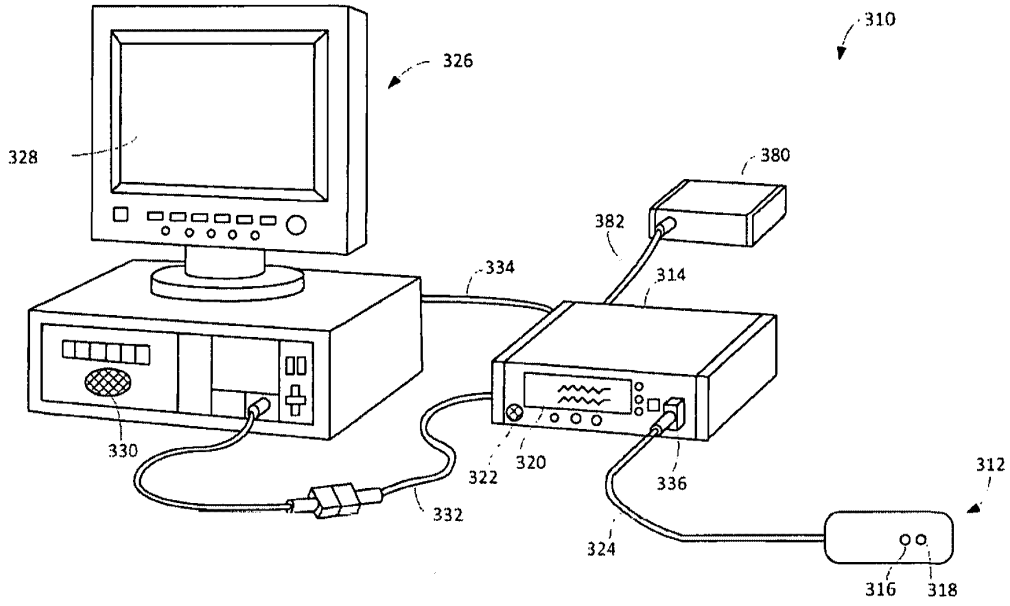


FIG. 3

Figure 3 of Lisogurski is "a perspective view of a physiological monitoring system." *Id.* at 2:23–25. The system includes sensor 312, monitor 314, and multi-parameter physiological monitor 326. *Id.* at 17:35–36, 18:44–45. Sensor 312 includes "one or more light sources 316 for emitting light at one or more wavelengths," and detector 318 for "detecting the light that is reflected by or has traveled through the subject's tissue." *Id.* at 17:37–42. Sensor 312 may have "[a]ny suitable configuration of light source 316 and detector 318," and "may include multiple light sources and detectors [that] may be spaced apart." *Id.* at 17:42–45. Light source 316 may include "LEDs of multiple wavelengths, for example a red LED and an IR [LED]." *Id.* at 19:25–27. Sensor 312 may be "wirelessly connected to monitor 314." *Id.* at 17:57–59.

Monitor 314 "calculate[s] physiological parameters based at least in part on data relating to light emission . . . received from one or more sensor units such as sensor unit 312." *Id.* at 17:59–62. Monitor 314 includes "display 320 . . . to display the physiological parameters," and "speaker 322 to provide an audible . . . alarm in the event a subject's physiological parameters are not within a predefined normal range." *Id.* at 18:3–10. Monitor 314 is "communicatively coupled to multi-parameter physiological monitor 326" ("MPPM 326") and "may communicate wirelessly" with MPPM 326. *Id.* at 18:58–61. Monitor 314 may also be "coupled to a network to enable the sharing of information with servers or other workstations." *Id.* at 18:62–65.

Multi-parameter physiological monitor 326 may also "calculate physiological parameters and . . . provide a display 328 for information from monitor 314." *Id.* at 18:49–52. MPPM 326 may also be "coupled to a network to enable the sharing of information with servers or other workstations." *Id.* at 18:62–65. The remote network servers may also "be used to determine physiological parameters," and may display the parameters on a remote display, display 320 of monitor 314, or display 328 of MPPM 326. *Id.* at 20:53–58. The remote servers may also "publish the data to a server or website," or otherwise "make them available to a user." *Id.* at 20:58–60.

Lisogurski discloses that the monitoring system shown in Figure 3, described above, "may include one or more components of physiological monitoring system 100 of FIG. 1." *Id.* at 17:32–35. Lisogurski further discloses that although "the components of physiological monitoring system 100 . . . are shown and described as separate components. . . . the

functionality of some of the components may be combined in a single component," and "the functionality of some of the components . . . may be divided over multiple components." *Id.* at 15:66–16:8. Figure 1 of Lisogurski is reproduced below.

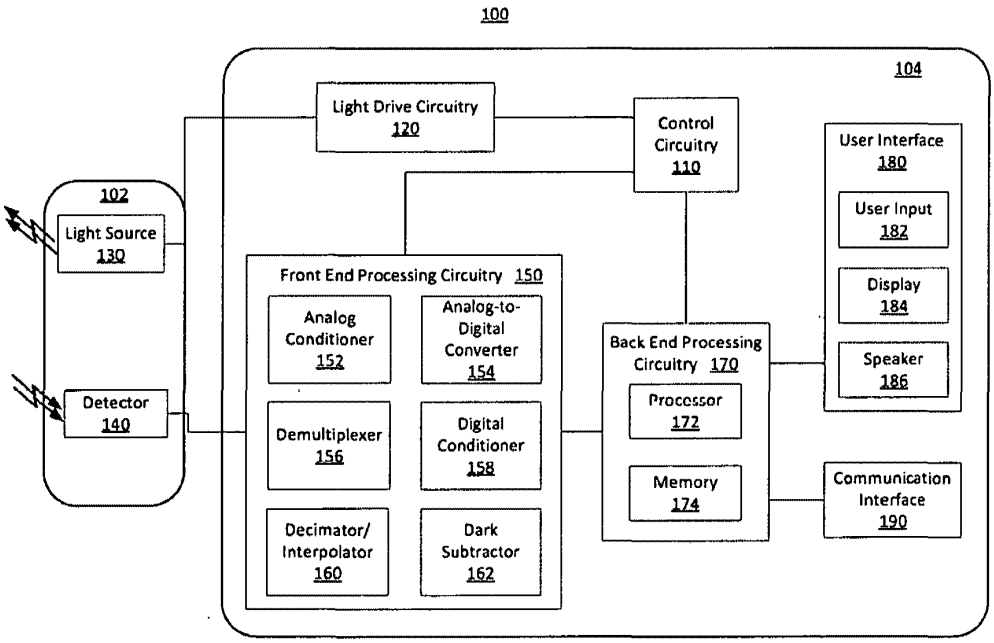


FIG. 1

Figure 1 of Lisogurski is a "block diagram of an illustrative physiological monitoring system." *Id.* at 2:11–13. The system includes "sensor 102 and monitor 104 for generating and processing physiological signals of a subject." *Id.* at 10:44–46. Sensor 102 includes "light source 130 and detector 140." *Id.* at 10:48–49. Light source 130 includes "a Red light emitting source and an IR light emitting source," such as Red and IR emitting LEDs, with the IR LED emitting light with a "wavelength between about 800 nm and 1000 nm." *Id.* at 10:52–58. Detector 140 "detect[s] the intensity of light at the Red and IR wavelengths," converts them to an

electrical signal, and "send[s] the detection signal to monitor 104, where the detection signal may be processed and physiological parameters determined." *Id.* at 11:9–10, 11:20–23.

Monitor 104 includes user interface 180, communication interface 190, and control circuitry 110 for controlling (a) light drive circuitry 120, (b) front end processing circuitry 150, and (c) back end processing circuitry 170 via "timing control signals." *Id.*, 11:33–38, Fig. 1. Light drive circuitry 120 "generate[s] a light drive signal . . . used to turn on and off the light source 130, based on the timing control signals." *Id.* at 11:38–40. The light drive signal "control[s] the intensity of light source 130 and the timing of when the light source 130 is turned on and off." *Id.* at 11:50–54. Front end processing circuitry 150 "receive[s] a detection signal from detector 140 and provides one or more processed signals to back end processing circuitry 170." *Id.* at 12:42–45. Front end processing circuitry 150 also "synchronize[s] the operation of an analog-to-digital converter and a demultiplexer with the light drive signal based on the timing control signals." *Id.* at 11:43–46.

Back end processing circuitry 170 "use[s] the timing control signals to coordinate its operation with front end processing circuitry 150." *Id.* at 11:46–49. Backend processing circuitry 170 includes processor 172 and memory 174, and "receive[s] and process[es] physiological signals received from front end processing circuitry 150" in order to "determine one or more physiological parameters." *Id.* at 14:56–57, 14:60–64. Backend processing circuitry 170 is "communicatively coupled [to] user interface 180 and communication interface 190." *Id.* at 15:16–18. User interface 180 includes "user input 182, display 184, and speaker 186," and may include "a

keyboard, a mouse, a touch screen, buttons, switches, [and] a microphone." *Id.* at 15:19–22. Communication interface 190 allows "monitor 104 to exchange information with external devices," and includes transmitters and receivers to allow wireless communications. *Id.* at 15:43–44, 15:48–57.

Lisogurski teaches the physiological monitoring system may modulate the light drive signal to have a "period the same as or closely related to the period of [a] cardiac cycle." *Id.* at 25:49–51. Thus, "[t]he system may vary parameters related to the light drive signal including drive current or light brightness, duty cycle, firing rate, . . . [and] other suitable parameters." *Id.* at 25:52–55. Lisogurski further teaches "the system may alter the cardiac cycle modulation technique based on the level of noise, ambient light, [and] other suitable reasons." *Id.* at 9:46–48. Thus, "[t]he system may increase the brightness of the light sources in response to [any] noise to improve the signal-to-noise ratio." *Id.* at 9:50–52. The system may also "change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light." *Id.* at 9:57–60.

2. Carlson

Carlson discloses an "optical pulsoximetry [device] used for non-invasive measurement of pulsation and oxygen saturation in arterial human or animal blood." Ex. 1009 ¶ 2. The device measures the light "absorption of reduced (Hb)—and oxidized (HbO_2) h[e]moglobin at two optical wavelengths, where the relative absorption coefficients differ significantly." *Id.* ¶ 3.

Figure 2 of Carlson is reproduced below.

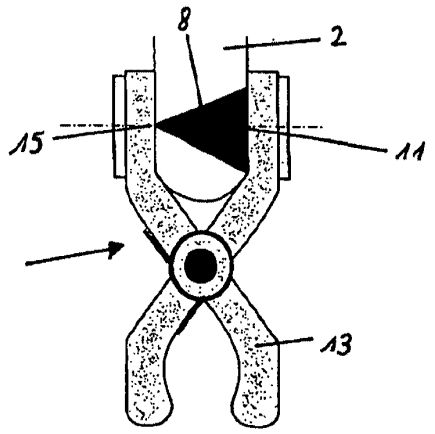


Figure 2

Figure 2 of Carlson is a schematic illustration of an ear clip sensor 1 of a pulsoximeter device. *Id.* ¶¶ 33, 49. Sensor 1 includes light source 15, which transmits light beam 8 through a patient's earlobe 2, and light detector 11 to detect the transmitted light. *Id.* ¶ 49. Light source 15 emits light at two wavelengths—660 nm and 890 nm—and can consist of two LEDs. *Id.* ¶ 50.

Carlson's pulsoximeter can be used to "survey the heath condition of a person or an animal [that] is mobile," and is "not restricted for use in, e.g., a hospital." *Id.* ¶ 72. Carlson teaches that "standard pulsoximeter sensors suffer from signal instability and insufficient robustness versus environmental disturbances." *Id.* ¶ 4. For example, when a sensor is worn by a person driving along a tree-lined avenue, the sensor will receive sunlight "at a certain frequency" such that "every time when passing a tree, sunlight is attenuated and between the trees sunlight is influencing the measurement of the pulsoximeter sensor." *Id.* ¶ 68. To address such problems, Carlson includes "optical and/or electronic means for increasing

Signal-to-Noise ratio (S/N) . . . of a pulsoximeter sensor for robust application of pulsoximetry in telemedicine- and near patient testing applications in rough (optical) environmental conditions." *Id.* ¶ 10. In particular, the LEDs in Carlson's sensor emit light "not as a current or continuous light but as pulsed light." *Id.* ¶ 69. Carlson's sensor also uses "AC-Coupling or Lock-In Amplification (synchronous detection) . . . to temporarily modulate the amplitude of the optical radiation of . . . the LED at a carrier frequency f_0 in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range." *Id.* ¶ 20. Modulation frequency f_0 is selected to be "outside the frequency spectrum of sunlight and of ambient light." *Id.* ¶ 69. This allows the pulsoximeter signal to be easily discriminated from environmental signals, such as sunlight and ambient light, and "increas[es] significantly the Signal-to-Noise and Signal-to-Background ratio." *Id.*

Carlson further discloses that sensor 1 can be wirelessly connected to "a special unit worn by [a] person or patient," where "a signal is generated if [a] measured value is not within a predetermined range." *Id.* ¶¶ 77–78. The generated signal can be "transmitted to a respective person, to a medical doctor, to a hospital, etc." *Id.* ¶ 78. The pulsoximeter can also include a "GPS device which at any time gives the location of the person using the pulsoximetric sensor monitoring configuration." *Id.*

3. Mannheimer

Mannheimer discloses a pulse oximetry device that "non-invasively measure[s] blood oxygen saturation of arterial blood in vivo." Ex. 1008, 1:10–13. Mannheimer's device performs a "pulsed oximetry measurement [that] isolates arterial saturation levels for particular ranges of tissue layers .

. . by utilizing multiple spaced detectors and/or emitters." *Id.* at 2:1–6.

Figure 1A of Mannheimer is reproduced below.

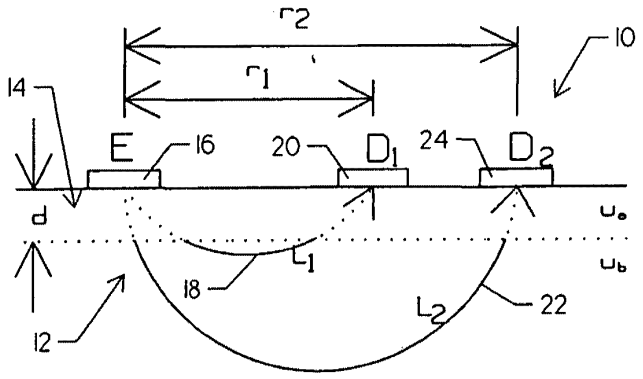


FIG. 1 A

Figure 1A of Mannheimer is a schematic diagram of a first embodiment of a pulse oximeter having one emitter 16 and two detectors 20/24. *Id.* at 2:40–42. Emitter 16 can be a single LED or multiple LEDs collocated to simulate a single point source. *Id.* at 3:13–18. Emitter 16 is separated from detector 20 by a first distance r_1, and is separated from detector 24 by a second distance r_2. *Id.* at 3:23–24. Light from emitter 16 is scattered by skin layer 14 and deeper skin layer 12, and reaches detectors 20/24 via respective paths 18/22. *Id.* at 3:18–20. Mannheimer calculates the blood oxygen concentration in skin layer 12 from the intensity of detected light at detectors 20/24 at two different times and two different wavelengths. *Id.* at 3:35–4:63.

In addition to the embodiment shown in Figure 1A, Mannheimer discloses a second embodiment of a pulse oximeter in Figure 1B, reproduced below.

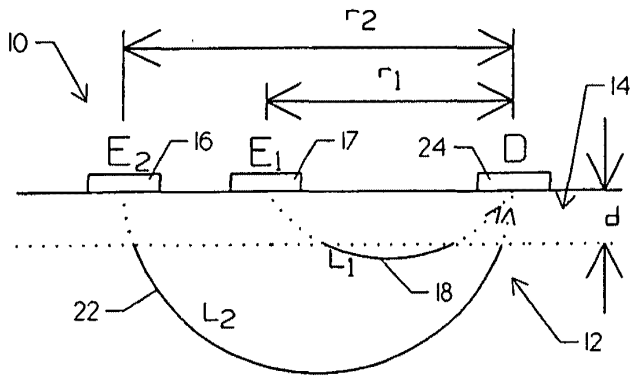


FIG. 1 B

Figure 1B of of Mannheimer is a schematic diagram of a second embodiment of a pulse oximeter having two emitters 16/17 and one detector 24. *Id.* at 2:43–44, 3:37–39. As shown in Figure 1B, emitter 17 is separated from detector 24 by a first distance r_1, and emitter 16 is separated from detector 24 by a second distance r_2. Mannheimer discloses that "[t]hose of skill in the art will appreciate that the operation" of the second embodiment shown in Figure 1B "is similar to that described above" in reference to the first embodiment shown in Figure 1A. *Id.* at 5:58–62.

F. Patentability of claims 5, 7–10, 13, and 15–17 over Lisogurski and Carlson

Petitioner argues claims 5, 7–10, 13, and 15–17 are unpatentable as obvious over the combination of Lisogurski and Carlson. *See* Pet. 21–63. At this stage of the proceeding, for the reasons stated below, we find Petitioner has demonstrated a reasonable likelihood of showing the unpatentability of these claims over Lisogurski and Carlson.

1. Petitioner's proposed combination

Petitioner proposes combining Lisogurski's physiological monitoring

system shown in Figures 1 and 3, in which sensor 102/312 wirelessly communicates with monitor 104/314, with Carlson's teachings regarding selecting an LED pulse frequency to increase signal-to-noise in a wireless pulse oximeter sensor. *See* Pet. 24–26, 32–34, 38–39, 41–44, 47–51. Petitioner's proposed combination relocates some of the components of Lisogurski's monitor 104/314 to sensor 102/312, as illustrated in a series of Petitioner-modified versions of Figure 1 of Lisogurski, which we combine below into a single modified version of Figure 1. *See id.* at 33, 47, 50.

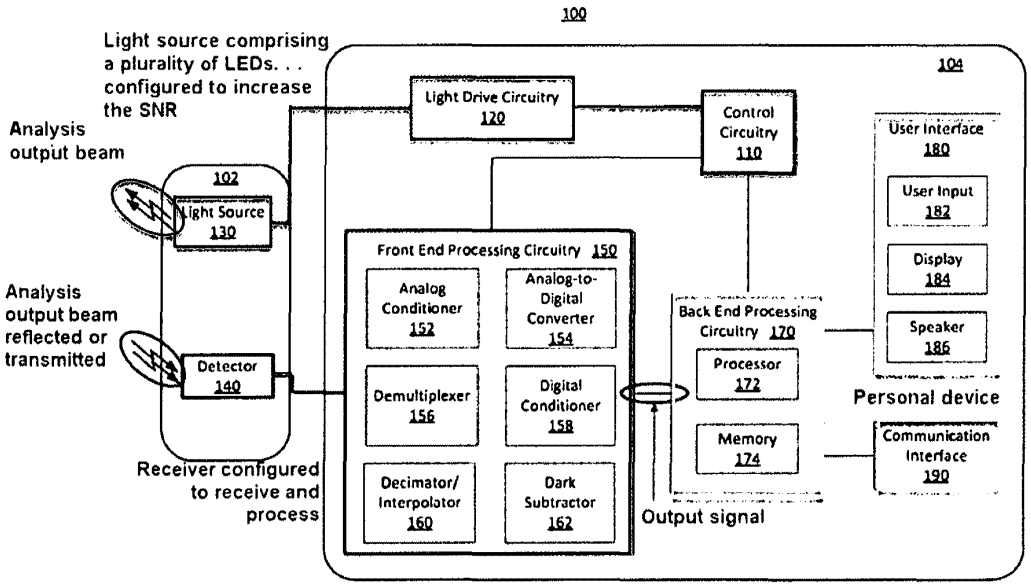


FIG. 1

Modified Figure 1 of Lisogurski demonstrates Petitioner's proposed combination, which relocates some components of monitor 104 (i.e., control circuitry 110, light drive circuitry 120, and front end processing circuitry 150) to sensor 102 as illustrated in the Petitioner-modified versions of Figure 1 provided in the Petition. *Id.*

Petitioner argues Lisogurski teaches or suggests these modifications

by teaching "[i]n some embodiments the functionality of some of the components may be combined in a single component . . . [or] the functionality of some of the components of monitor 104 . . . may be divided over multiple components." *Id.* at 33–34, 49 (quoting Ex. 1011, 16:2–9; citing Ex. 1003 ¶¶ 102, 145). Petitioner further argues that general industry trends suggest these modifications by teaching adding and integrating "features and capabilities of wearable devices to improve their operation in mobile monitoring systems or for sports and personal fitness applications." *Id.* at 34, 49 (citing Ex. 1003 ¶¶ 103, 146); *see also id.* at 26 (citing Ex. 1003 ¶¶ 48–56).

Petitioner identifies several industry trends that it argues teach or suggest its proposed modifications to Lisogurski's sensor 102/312 and monitor 104/314. The first was the "development of wireless monitoring technologies that could be worn by the patient and used to transmit data to a remote physician or care provider" in order to "respond to the challenge of providing medical care for patients in their homes or in locations where there was not easy access to a physician." *Id.* at 6–7 (citing Ex. 1003 ¶¶ 52–53; Ex. 1021, 2 ("[r]emote monitoring systems have the potential to mitigate problematic patient access issues"); Ex. 1024, 462 ("wireless technology promises benefits for medical monitoring applications by freeing patients from inconvenient and restrictive wires" allowing them to "remain in their homes while still under medical supervision"); Ex. 1027, 15 (disclosing growth in the remote patient monitoring market "exceeding expectations" and not being negatively impacted by the 2009 financial crisis).

The second industry trend was "bring[ing] heart rate sensing devices based on pulsoximetry to the consumer market for personal fitness tracking

and other uses." *Id.* at 7 (citing Ex. 1003 ¶¶ 49–50; Ex. 1005 ¶ 3 ("[t]here is a growing market demand for personal health . . . monitors"); Ex. 1009 ¶ 4 ("[p]ulsoximetry measuring devices are also used in sports for control and survey of athletes"); Ex. 1020, 3 ("[a] multitude of commercial health devices and sensors, such as oximeters and heart rate monitors, formerly reserved for professional use . . . can now be connected to smartphones"); Ex. 1027, 33, 35; Ex. 1029, 221).

The third industry trend was "tak[ing] advantage of the miniaturization of electronics and communication technology, which led to the development of smaller, wearable monitoring systems for mobile health and fitness applications." *Id.* (citing 1003 ¶¶ 51–52; Ex. 1021, 3 ("[r]ecent advances in sensor technology, microelectronics, telecommunication, and data analysis techniques have enabled the development of wearable systems for patients' remote monitoring"); Ex. 1022, 1).

The fourth industry trend was the medical industry's use of "apps and smartphones to not only deliver care to patients but to give individual access to health data for fitness or health issues." *Id.* at 7–8 (citing Ex. 1003 ¶¶ 51–52; Ex. 1021, 4 (transmitting "data gathered using sensor networks . . . to a remote site such as a hospital server" via "an information gateway such as a mobile phone or personal computer"); Ex. 1023, 5–6 (disclosing the biggest drivers for medical usage of tablets are "[p]atient monitoring and data collection," "[d]ashboard and [r]eports, "[a]ppointment scheduling," and "[p]rescriptions, authorizations, refills, patient-drug interaction and dosage management"); Ex. 1027 9, 10, 40–49). Petitioner argues these industry trends "provided a strong motivation to skilled persons to integrate medical optical sensing techniques into miniaturized wearable consumer devices that

communicate wirelessly with smart devices and remote services." *Id.* at 8 (citing Ex. 1003 ¶¶ 49–50).

Petitioner argues the teachings of Lisogurski and Carlson are combinable because both references "concern analogous miniaturized wireless puloximetry devices having the same applications (*e.g.*, mobile monitoring of pulse and other physiological characteristics of a person)." *Id.* at 24 (citing Ex. 1003 ¶ 84). Specifically, Petitioner argues Lisogurski teaches a pulse oximetry system that includes a wearable sensor that "increas[es] the signal-to-noise of measured signals while minimizing power consumption." *Id.* at 25 (citing Ex. 1011, 4:15–20, 9:46–52, 17:51–58). Petitioner argues that Carlson teaches improving wearable pulse oximetry devices "by improving both signal measurement and energy consumption." *Id.* (citing Ex. 1009 ¶¶ 2, 10, 48, 52; Ex. 1003 ¶ 83). Therefore, Petitioner argues, a person skilled in the art would have had reason to combine the teachings of Lisogurski and Carlson "as part of the ordinary design process he or she follows to improve the operation of a device" because both references teach "techniques for achieving the same objectives." *Id.* at 24 (citing Ex. 1003 ¶¶ 81–84). Namely, Petitioner argues, "[b]oth references identify the same problem – ambient light – and the need to offset its negative impact on the signal-to-noise ratio." *Id.* at 38 (citing Ex. 1011, 9:46–60; Ex. 1009 ¶¶ 67–69; Ex. 1003 ¶¶ 118–121).

Patent Owner argues that Lisogurki's sensor 102/312 is not a wearable measurement device having a receiver configured to receive and process an analysis output beam because "processing circuitry 150 is part of the monitor 104, not part of the sensor 102 'placed' on a patient." Prelim. Resp. 28. Patent Owner argues that because Lisogurski teaches sensor 102/312 is

a medical device, a person skilled in the art would have had no reason "to add sensitive circuitry to the sensor of such a medical device used in a medical setting." *Id.* at 29–30. To the contrary, Patent Owner argues, a person skilled in the art "would have wanted the components of Lisogurski's system, especially the sensor unit, to be simple and inexpensive so they could be easily and inexpensively sanitized or disposed of between patients." *Id.* at 30. Patent Owner similarly argues that Lisogurski's monitor 104/314 is not a personal device because monitor 104/314, as modified by Petitioner, "is not disclosed in Lisogurski." *Id.* at 23. Patent Owner argues Petitioner's proposed modification of monitor 104/314 relies on hindsight "to artificially select components of a monitor 104 and assert they are a '*personal device*,' while deselecting other components . . . and asserting they are part of a 'wearable device.'" *Id.*

At this stage of the proceeding, we find Petitioner has demonstrated a reasonable likelihood of showing why a person of ordinary skill in the art would have modified Lisogurski's sensor 102/312 and monitor 104/314 in the manner proposed by Petitioner, and would have incorporated the teachings of Carlson. First, Lisogurski expressly suggests the modifications by teaching some components of monitor 104/314 can be divided among multiple components. *See* Ex. 1011, 16:7–9. Moreover, the industry trends identified by Petitioner, including wirelessly connecting wearable sensors to a network to remotely monitor patients, motivate the proposed combination. *See* Ex. 1005 ¶ 3; Ex. 1009 ¶ 4; Ex. 1020, 3; Ex. 1021, 2–4; Ex. 1022, 1; Ex. 1024, 462, Ex. 1027, 9, 10, 15, 33, 35, 40–49; Ex. 1029, 221; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("When a work is available in one field of endeavor, design incentives and other market forces

can prompt variations of it. . . . If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.").

Petitioner has also demonstrated a reasonable likelihood of showing why a person of ordinary skill in the art would have modified Lisogurski's LED light source to increase pulse rate to improve the signal-to-noise ratio. Lisogurski and Carlson teach complementary methods of increasing signal-to-noise in the presence of noise. Specifically, Lisogurski teaches increasing LED intensity, and Carlson teaches pulsing the LEDs at a rate higher than the frequency spectrum of the noise. *See* Ex. 1011, 9:50–52 ("The system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio."); Ex. 1009 ¶ 69 ("emit[ting] light by the LEDs not as current or continuous light but as pulsed light. The frequency is chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light. . . . increasing significantly the Signal-to-Noise."). Significantly, Petitioner's reasons for combining the teachings of Lisogurski and Carlson depend only on the teachings of Lisogurski and Carlson. They do not depend on any teachings from the '533 patent, and, therefore, do not depend on hindsight. *See In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

2. Claims 5 and 13

Claim 13 recites a measurement system, and requires the system to include a wearable measurement device for measuring one or more physiological parameters. Ex. 1001 30:46–48. Petitioner argues that Lisogurski's measurement system 100/310, including sensor 102/312 for measuring blood oxygen saturation, meets this limitation. *See* Pet. 28 (citing Ex. 1011, 4:6–20, 17:55–59). Patent Owner argues Lisogurski's sensor

102/312, when modified as discussed in § II.F.1, *supra*, is not a wearable measurement device. *See* Prelim. Resp. 26–30. At this stage of the proceeding, for the reasons discussed above and notwithstanding Patent Owner's arguments to the contrary, we find Petitioner has sufficiently demonstrated that Lisogurski's sensor 102/312 is a wearable measurement device. Sensor 102/312 is a pulse oximeter that can be battery powered, wirelessly connected to monitor 104/314, and mounted on a user's fingertip, toe, earlobe, wrist, or thigh. Ex. 1011, 4:6–8, 4:15–20, 17:55–59.

Claim 13 further requires the wearable measurement device to include a light source that includes a plurality of semiconductor sources that are light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, including a near-infrared wavelength between 700 and 2500 nanometers. Ex. 1001 30:48–55. Petitioner sufficiently demonstrates, at this stage of the proceeding, how Lisogurski's sensor 102/312 meets this limitation. *See* Pet. 29–30 (citing Ex. 1011, 4:42–45, 7:38–8:3, 10:48–52, 10:56–63, 17:37–45, 19:25–31, Figs. 1, 3; Ex. 1003 ¶¶ 92–94). Sensor 102/312 can contain multiple LEDs that emit and direct light toward a subject's tissue, including an LED that emits red light, and an LED that emits infrared light having a wavelength between 800 and 1000 nm. Ex. 1011, 10:48–52, 10:56–63.

Claim 13 further requires the light source to be configured to increase signal-to-noise by increasing a light intensity of at least one of the plurality of semiconductor sources. Ex. 1001 30:56–58. Petitioner sufficiently demonstrates, at this stage of the proceeding, how Lisogurski's LED-based

light source 130/316 meets this limitation.[6] *See* Pet. 30–31 (citing Ex. 1011, 1:19–21, 1:44–46, 1:67–2:3, 5:55–6:6, 9:46–52, 9:57–60, 10:48–49, 11:38–41, 11:50–54, 14:49–55, 35:5–9; Ex. 1003 ¶¶ 95–98). Lisogurski teaches "the intensity of light source 130 and the timing of when light source 130 is turned on and off" is controlled by a light drive signal that "increase[s] the brightness of the light sources in response to . . . noise to improve the signal-to-noise ratio." Ex. 1011, 9:50–52, 11:50–54.

Claim 13 further requires the light source to be configured to increase signal-to-noise by increasing a pulse rate of at least one of the plurality of semiconductor sources. Ex. 1001 30:58–60. Petitioner first argues that Lisogurski alone teaches this limitation by teaching (1) the LED firing rate can be modified by the light drive signal, (2) the LED firing rate is correlated to the detector sampling rate, (3) the detector sampling rate can be varied in the same way as the LED light output, and (4) the LED light output can be increased to increase signal-to-noise. *See* Pet. 35–36 (citing Ex.

[6] Petitioner argues that to the extent the claim requires the circuitry that controls and drives light source 130/316 must be in sensor 102/312, that configuration would have been obvious in view of the teachings in Lisogurski and the industry trends discussed in § II.F.1, *supra*. *See* Pet. 32–34 (citing Ex. 1011, 16:2–9, 17:32–35, 17:55–59, 18:16–31; Ex. 1003 ¶¶ 99–103). Although we do not construe the claims to require the light source to include the circuitry that allows it to be configured to increase signal-to-noise ratio, Petitioner has sufficiently demonstrated that it would have been obvious to move the light drive circuitry from monitor 104/314 to wireless sensor 102/312 for the reasons discussed in § II.F.1, *supra*.

1011, 2:1–2, 8:29–35, 9:46–52, 11:43–46, 11:52–55, 25:49–55, 33:47–49, 33:56–58, 35:7–9; 35:27–31, 37:6–22; Ex. 1003 ¶¶ 112–116).

Patent Owner argues that Lisogurski's light source is not configured to increase signal-to-noise by increasing LED firing rate for several reasons. *See* Prelim. Resp. 16–20. First, Patent Owner argues that adjusting Lisogurski's "'sampling rate' has nothing to do with adjusting the firing rate of the LEDs." *Id.* (citing Ex. 1011, 10:23–26, 34:10–12). Second, Patent Owner argues that Lisogurski teaches adjusting LED firing rate "to reduce power consumption, to synchronize with physiological impulses, to respond to an external trigger, or to change sampling rates," but not to improve signal-to-noise. *Id.* at 18–19 (quoting Ex. 1011 [57], 25:46–55, 35:24–31). Finally, Patent Owner argues that Lisogurski teaches away from increasing LED firing rate to increase signal-to-noise because it teaches "chang[ing] from a modulated output to a constant light output in response to noise, patient motion, or ambient light." *Id.* at 19 (quoting Ex. 1011, 9:57–60) (emphasis omitted).

At this stage of the proceeding, Petitioner has failed to sufficiently demonstrate how Lisogurski teaches increasing LED firing rate to increase signal-to-noise. The passages of Lisogurski identified by Petitioner teach generating a light drive signal that "varies with a period the same as or closely related to the period of the cardiac cycle" by varying parameters "related to the light drive signal including drive current or light brightness, duty cycle, firing rate . . . [and] other suitable parameters." Ex. 1011, 25:49–55. That is, the LED firing rate is varied to become or remain synchronous with a cardiac cycle, not to increase signal-to-noise. Although Lisogurski teaches "alter[ing] the cardiac cycle modulation technique based on the level

of noise [or] ambient light," Lisogurski teaches doing this by "increasing the brightness of the light sources" or by changing "from a modulated light output to a constant light output." *Id.* at 9:46–60.

Similarly, although Lisogurski teaches light output variations may also apply to sampling rate, this teaching in Lisogurski is provided in the context of modifying the sampling rate, light output, and other parameters to be synchronous with cardiac cycles:

> It will also be understood that sampling rate is one of the components that may be modulated in cardiac cycle modulation as described above. It will also be understood that the earlier described embodiments relating to varying light output may also apply to sampling rate.

Id. at 35:5–9. Throughout the specification, Lisogurski teaches varying light intensity to be synchronous with features of a cardiac cycle. *See id.* at 20:64–67 ("us[ing] a first light drive signal to identify systole periods of the cardiac cycle and modulat[ing] a second light drive signal to increase light intensity concurrent with the systole periods"); 22:14–17 ("us[ing] a first light drive signal to identify diastole . . . periods of the cardiac cycle and modulat[ing] a second light drive signal to increase light intensity concurrent with diastole period[s]"); 22:51–54 ("us[ing] a first light drive signal to identify a dicrotic notch . . . in the cardiac cycle and modulat[ing] a second light drive signal to increase light intensity concurrent with the dicrotic notch"). Thus, when Lisogurski teaches "varying light output may also apply to sampling rate," Lisogurski is teaching varying the sampling rate to be synchronous with the cardiac cycle, not to improve signal-to-noise. *Id.* at 35:5–9.

Petitioner next argues that to the extent Lisogurski does not teach increasing LED firing rates to increase signal-to-noise, it would have been obvious to modify Lisogurski to do so in view of the teachings of Carlson. *See id.* at 37–39. Specifically, Petitioner argues that Lisogurski "clearly identifies the importance of increasing signal-to-noise ratio" by increasing LED intensity to increase signal-to-noise. *Id.* at 37 (citing Ex. 1011, 9:50–52). Therefore, Petitioner argues, a person skilled in the art "would have been motivated to consider prior art teaching additional ways of improving signal-to-noise ratio in optical sensors based on LEDs." *Id.* (citing Ex. 1003 ¶¶ 83–85, 120–121). Petitioner argues Carlson teaches such a method, and improves a pulse oximeter's signal-to-noise by pulsing the oximeter's LEDs at a frequency that is "outside the frequency spectrum of sunlight and of ambient light" in order to "reduce[] the effects of ambient light including sunlight." *Id.* at 37–38 (citing Ex. 1009 ¶¶ 67–69; Ex. 1003 ¶¶ 118–119).

Petitioner argues that it would have been obvious to modify Lisogurski based on the teachings of Carlson because both references recognize the problem of ambient light noise "and the need to offset its negative impact on the signal-to-noise ratio." *Id.* at 38 (citing Ex. 1009 ¶¶ 67–69; Ex. 1011 9:46–60; Ex. 1003 ¶¶ 118–121). Petitioner further argues that it would be straightforward to modify Lisogurski to incorporate the teachings of Carlson because Lisogurski already teaches (a) modifying the LED firing rate in response to changing conditions, and (b) modifying the light drive signal in response to changes in ambient light and other sources of noise. *Id.* (citing Ex. 1011, 1:67–2:3, 5:55–61, 9:46–60, 37:6–18; Ex. 1003 ¶¶ 120–122).

Patent Owner argues Lisogurski teaches away from the combination by teaching "[i]n some embodiments, the system may change from a modulated output to a constant light output in response to noise, patient motion, or ambient light." Prelim. Resp. 19 (quoting Ex. 1011, 9:57–60) (emphasis omitted). Patent Owner argues that because this passage teaches "decreasing the pulse rate from a modulated light output to a constant light output," a person of ordinary skill in the art "would not be inclined to modify Lisogurski 'to increase signal-to-noise . . . by increasing a pulse rate." *Id.* (emphasis omitted).

At this stage of the proceeding, notwithstanding Patent Owner's argument to the contrary, we find Petitioner has sufficiently demonstrated reasoning with rational underpinning to combine the teachings of Lisogurski and Carlson. Lisogurski does not teach away from the combination because Lisogurski does not criticize, discredit, or otherwise discourage improving signal-to-noise by increasing the LED firing rate. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Rather, Lisogurski teaches alternative ways of improving signal-to-noise by increasing the total amount of light delivered to a sample, including by (a) discontinuing cardiac cycle modulation, (b) increasing emitter intensity during cardiac cycle modulation, or (c) increasing the duty cycle or "on" periods of cardiac cycle modulation. *See* Ex. 1011, 9:46–60, 37:6–20. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from . . . alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed." *Fulton* 391 F.3d at 1201.

Patent Owner next argues that Carlson does not teach increasing LED firing rate in response to increased noise, but instead teaches "choos[ing] a

particular fixed pulsed frequency to avoid ambient light and sunlight." Prelim. Resp. 20. Specifically, Patent Owner argues that Carlson "does not disclose 'increasing a pulse rate' of at least one of the semiconductor sources while in use, but instead merely teaches choosing, while designing a product, a particular frequency to avoid certain types of light." *Id.* at 21 (citing Ex. 1005 ¶ 69).

At this stage of the proceeding, notwithstanding Patent Owner's argument to the contrary, we find Petitioner has sufficiently demonstrated reasoning with rational underpinning to combine the teachings of Lisogurski and Carlson. Carlson teaches that "standard pulsoximeter sensors suffer from signal instability and insufficient robustness versus environmental disturbances," and provides, as an example, disturbances caused when a person wearing a sensor experiences alternating cycles of sunshine and shade "at a certain frequency" while walking or driving along a tree-lined avenue. Ex. 1009 ¶¶ 4, 68. Carlson teaches removing such disturbances by pulsing the sensor LEDs at a frequency that is "outside the frequency spectrum of sunlight[7] and of ambient light" in order to "increas[e] significantly the Signal-to-Noise." *Id.* ¶ 69. Carlson does not teach pulsing the LEDs at any particular frequency, but instead teaches pulsing at some

[7] Carlson identifies the "frequency spectrum" of sunlight as 0 Hz. *See* Ex. 1005, Fig. 7b. We understand this passage of Carlson to be referring to the frequency of alternating periods of sunshine and shade, rather than to the actual frequency spectrum of sunlight, which is quite broad. The frequency spectrum of alternating periods of sunshine and shade would be 0 Hz when a person is standing in continual sunshine or continual shade, but would increase when travelling down a tree-lined street based on the spacing between trees and the speed of travel. *Id.* ¶ 68.

frequency f_0 and "using AC-Coupling or Lock-In Amplification . . . to temporarily modulate the optical radiation of the LED at the carrier frequency f_0 in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶¶ 65, 69. Although Carlson gives a particular example of pulsing the LEDs at 1000 Hz, that example pertains to sampling pulsed LED light that has been transmitted through or reflected from a sample in the presence of 0 to 120 Hz noise. *Id.* ¶ 69. Carlson more generally teaches "shift[ing] the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶ 65.

Moreover, even accepting as true Patent Owner's argument that Carlson teaches selecting a single (e.g., 1000 Hz) LED pulse rate when designing the pulsoximeter, Patent Owner's argument fails to consider the combined teachings of Carlson and Lisogurski. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references."); *see also In re Keller 642 F.2d 413, 425* (Fed. Cir. 1981) (the test for obviousness is "what the combined teachings of the references would have suggested to those of ordinary skill in the art").

Lisogurski teaches varying a pulsoximeter's light drive signal, including an LED firing rate, based on a received external trigger. Ex. 1011 1:60–2:3. Lisogurski also teaches "detect[ing] a change in background noise [or] ambient light." *Id.* at 37:8–9. Lisogurski further teaches using servo algorithms to "adjust the light drive signals due to, for example, ambient

light changes." *Id.* at 5:55–59. Carlson teaches increasing a pulsoximeter's signal-to-noise in the presence of ambient light by choosing the LED firing rate or pulse frequency to be "outside the frequency spectrum of sunlight and of ambient light." Ex. 1009 ¶ 69. Together, the references teach that a pulsoximeter can detect a change in background noise and modify the LED firing rate based on the detected change (as taught by Lisogurski), and can modify the frequency of the LED firing rate to be greater than the frequency of the background noise (as taught by Carlson). *See* e.g., Ex. 1011, 37:6–9, 1:67–2:3; Ex. 1009 ¶¶ 65, 69. For these reasons, at this stage of the proceeding, Petitioner has sufficiently demonstrated that "a skilled person would have found it obvious to configure Lisogurski to increase the firing rate (frequency) of LEDs as taught by Carlson." Pet. 39.

Claim 13 further requires the wearable measurement device to include a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample. Ex. 1001 30:60–63. Petitioner argues that a person of ordinary skill in the art would have known that LEDs are either (i) not covered by an encapsulant, (ii) covered by an optically inert encapsulant, or (iii) covered by a lensing encapsulant. Pet. 39–40 (citing Ex. 1003 ¶¶ 124–125; Ex. 1035, 97–98, 191–199, 266–267). Petitioner argues a person skilled in the art would have selected the LEDs in Lisogurski's light source to have lensing encapsulants because "this was a common configuration with known benefits." *Id.* at 40–41 (citing Ex. 1019, 765; Ex. 1003 ¶¶ 124–129). For example, Petitioner argues Carlson teaches the benefits of using lenses to focus LED light onto a sample. *Id.* at 41–42 (citing Ex. 1009 ¶¶ 13, 14, 24, 62, Fig. 4; Ex. 1003 ¶¶ 130–133). Figure 4 of Carlson is reproduced below.

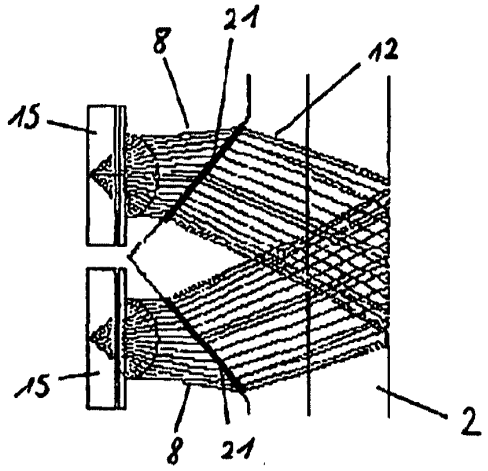


Figure 4

Figure 4 of Carlson is a schematic illustration of "two light emitting sources for an oximetric sensor, including beam shaping optics." Ex. 1009 ¶ 35. Petitioner argues Figure 4 of Carlson shows "two lenses 21 that receive light beams 8 emitted by LEDs 15 . . . and deliver light bundles or beams 12 to sample 2." Pet. 42 (citing Ex. 1009 ¶¶ 54, 62). Petitioner argues a person skilled in the art would have selected Lisogurski's LEDs to have lensing encapsulents because Lisogurski teaches reducing power consumption while maintaining signal-to-noise, and Carlson teaches using lenses to "increase the optical signal power without increasing the actual power used by the system." *Id.* at 43 (citing Ex. 1009 ¶¶ 10, 14). For these reasons, at this stage of the proceeding, Petitioner has sufficiently demonstrated that a person skilled in the art would have selected Lisogurski's LEDs to have encapsulated lenses.

Claim 13 further requires the wearable measurement device to include a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an

output signal, and further configured to be synchronized to pulses of the light source. Ex. 1001 30:64–31:3. Petitioner identifies Lisogurski's detector 140/318 and front end processing circuitry 150 in monitor 104 as the receiver. *See* Pet. 45 ("The detector described in Lisogurski is connected to front end processing circuitry (together a '*receiver configured to receive and process*')"). Petitioner provides a modified version of Figure 1 of Lisogurski, reproduced below, to illustrate the components of such a receiver.

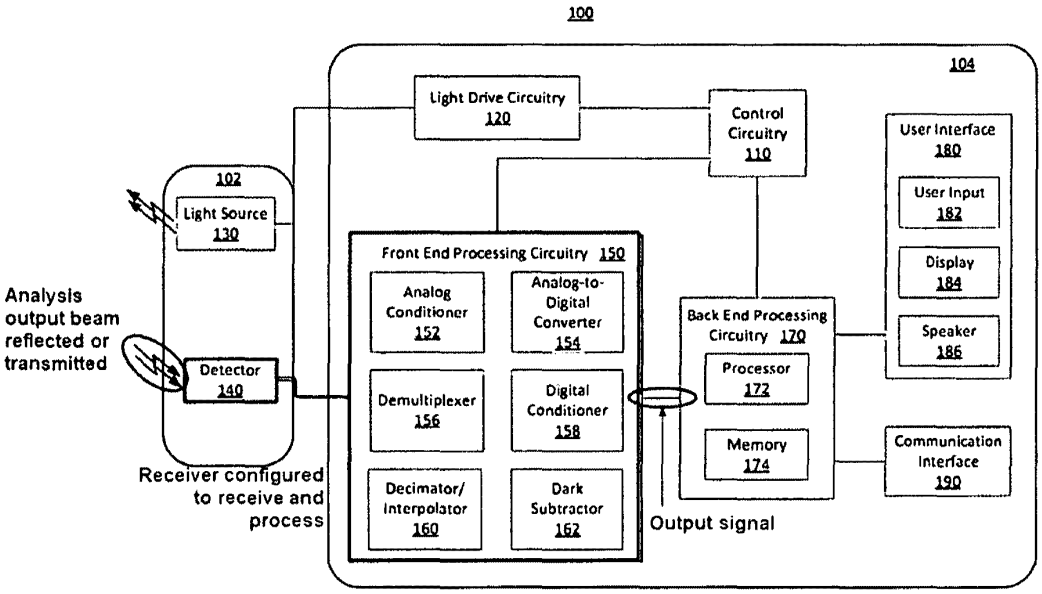


FIG. 1

Modified Figure 1 of Lisogurski is a Petitioner-modified version of Figure 1 of Lisogurski showing Petitioner's proposed modification of sensor 102 to include front end processing circuitry 150 from monitor 104.

Petitioner argues Lisogurski's detector 140/318 and front end processing circuitry 150 is a receiver configured to receive at least a portion of the analysis output beam because detector 140/318 "receives 'the light

that is reflected by or has traveled through the subject's tissue.'" *Id.* at 44 (quoting Ex. 1011, 17:40–42; citing Ex. 1011, 11:9–10, Figs. 1, 3). Petitioner argues detector 140/318 and front end processing circuitry 150 process at least a portion of the analysis output beam to generate an output signal because detector 140/318 "convert[s] the intensity of the received light into an electrical signal," and sends it to front end processing circuitry 150, which "receive[s] a detection signal from detector 140 and provide[s] one or more processed signals to back end processing circuitry 170." *Id.* at 44–45 (quoting Ex. 1011, 11:14–17, 12:42–45; citing Ex. 1011, 11:20–27). Petitioner argues detector 140/318 and front end processing circuitry 150 are synchronized to pulses of the light source because "front end processing circuitry may use the timing control signals to operate synchronously with light drive circuitry 120," which drives Lisogurski's LED-based light source. *Id.* at 45 (quoting Ex. 1011, 11:41–46; citing Ex. 1003 ¶ 139).

Petitioner argues a person skilled in the art would have modified Lisogurski's sensor 102/312 to include front end processing circuitry 150 for the reasons discussed in § II.F.1, *supra*. Namely, that in Lisogurski's wireless embodiment of sensor 102/312, a person skilled in the art "would have found it obvious to include the front end processing circuitry, which performs analog-to-digital conversion and other initial processing of the signal, in the sensor where the signal is captured," to allow the sensor to "process the detected signal and wirelessly transmit it to the monitor." *Id.* at 48 (citing Ex. 1003 ¶ 144). Next, Petitioner argues Lisogurski suggests the modification by teaching that "[in] some embodiments the functionality of some of the components may be combined in a single component . . . [or] the functionality of some of the components of monitor 104 . . . may be

divided over multiple components." *Id.* at 49 (quoting Ex. 1011, 16:2–9; citing Ex. 1003 ¶ 145). Lastly, Petitioner argues the modification would have been obvious in view of industry trends at the time, including the industry trends discussed in § II.F.1, *supra*. *Id.* (citing Ex. 1003 ¶ 146).

Patent Owner argues Lisogurski's sensor 102/312 is not a wearable measurement device having the claimed receiver because "processing circuitry 150 is part of the monitor 104, not party of the sensor 102 'placed' on a patient." Prelim. Resp. 28. Patent Owner further argues a person skilled in the art would not have included processing circuitry 150 in sensor 102/312 because Lisogurski describes a medical device, and "[t]here would have been no rationale or reason for an ordinary practitioner to add sensitive circuitry to the sensor of such a medical device used in a medical setting." *Id.* at 29–30. We are not persuaded by Patent Owner's arguments for the reasons discussed in § II.F.1, *supra*. Namely, Lisogurski expressly suggests the modifications, as do the industry trends identified by Petitioner such as wirelessly connecting wearable sensors to a network to remotely monitor patients. *See* Ex. 1005 ¶ 3; Ex. 1009 ¶ 4; Ex. 1020, 3; Ex. 1021, 2–4; Ex. 1022, 1; Ex. 1024, 462, Ex. 1027, 9, 10, 15, 33, 35, 40–49; Ex. 1029, 221; *see also KSR*, 550 U.S. at 418.

Claim 13 further requires a personal device that includes a wireless receiver and transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen. Ex. 1001 31:3–7. Petitioner identifies backend processing circuitry 170, user interface 180, and communication interface 190 of Lisogurski's monitor 104/314 as the personal device. *See* Pet. 49–53. Petitioner argues backend processing circuitry 170 includes microprocessor 172, user interface 180 includes a

display, a microphone, a speaker, buttons, and a touch screen, and communication interface 190 includes wireless receivers and transmitters for wireless communications. *Id.* at 51 (citing Ex. 1011, 15:19–23, 15:49–56, Fig. 1).

Claim 13 further requires the personal device to be configured to receive and process at least a portion of the output signal, to store and display the processed output signal, and to transmit at least a portion of the processed output signal over a wireless transmission link. Ex. 1001 31:7–12. Petitioner argues processor 172 receives the output signal from front end processing circuitry 150, and processes that signal to "determine one or more physiological parameters based on the received physiological signals." *Id.* at 50–51 (citing Ex. 1011, 14:60–64). Petitioner argues back end processing circuitry 170 displays the calculated physiological parameters, such as "a subject's blood oxygen saturation . . . [and] pulse rate information" on a display. *Id.* at 51 (citing Ex. 1011, 14:62–64, 15:30–35).

As discussed in § II.F.1, *supra*, Patent Owner argues that Lisogurski's monitor 104/314 is not a personal device because the monitor 104/314 as modified by Petitioner "is not disclosed in Lisogurski." Prelim. Resp. 23. Patent Owner argues Petitioner's proposed modifications of monitor 104/314 relies on hindsight "to artificially select components of a monitor 104 and assert they are a '*personal device*,' while deselecting other components . . . and asserting they are part of a 'wearable device.'" *Id.* At this stage of the proceeding, we are not persuaded by Patent Owner's arguments for the reasons discussed in § II.F.1, *supra*. Namely, Lisogurski expressly suggests the modifications to monitor 104/314 by teaching some components of monitor 104/314 can be divided among multiple components,

as do the industry trends identified by Petitioner. *See* Ex. 1011, 16:7–9; Ex. 1005 ¶ 3; Ex. 1009 ¶ 4; Ex. 1020, 3; Ex. 1021, 2–4; Ex. 1022, 1; Ex. 1024, 462, Ex. 1027, 9, 10, 15, 33, 35, 40–49; Ex. 1029, 221; *see also KSR* 550 U.S. at 418.

Claim 13 further requires a remote device configured to receive over the wireless transmission link an output status including at least a portion of the processed output signal, to process the received output status to generate and store processed data, and to store a history of at least a portion of the received output status over a specified period of time. Ex. 1001 31:13–20.

Petitioner sufficiently demonstrates, at this stage of the proceeding, how Lisogurski's multi-parameter physiological monitor 326 or remote servers or workstations meet these limitations. *See* Pet. 53–55 (citing Ex. 1011, 15:43–48, 18:49–53, 18:58–62, 20:8–13, 26:51–60; Ex. 1003 ¶¶ 154–163). Lisogurski teaches monitor 104/314 can wirelessly "exchange information with [an] external device," such as "a network, a server or other workstation[]," and can "publish [its] data to a server or website." Ex. 1011, 15:43–48, 26:55–60. Multi-parameter physiological monitor 326 is an example of such a workstation, and can "calculate physiological parameters and . . . provide a display for information from monitor 314 and from other medical monitoring devices." *Id.* at 18:49–53, Fig. 3.

Monitor 104/314 can also "be coupled to a network or enable the sharing of information with servers or other workstations," and Lisogurski teaches that "processing equipment remote to [its] system may be used to determine physiological parameters." *Id.* at 18:62–65, 26:53–55. According to Dr. Anthony, "[a] person of ordinary skill would understand that these devices generate and store processed data in order to perform these

functions." Ex, 1003 ¶¶ 156–157. Lisogurski further teaches that its systems can store historical data and perform statistical analyses on that data. *Id.* at 20:8–13. According to Dr. Anthony, "[a] person of ordinary skill would . . . understand that the remote device (whether it is a server, website, another monitor, or another device with memory and processing capability) stores a history of the data and can perform an historical analysis." Ex. 1003 ¶ 163.

For the reasons discussed above, and notwithstanding Patent Owner's arguments to the contrary, at this stage of the proceeding Petitioner demonstrates a reasonable likelihood of showing claim 13 is unpatentable over the combination of Lisogurski and Carlson. Moreover, as discussed in § II.B, *supra*, claim 5, is substantially similar to but broader than claim 13 because it does not recite all of the limitations of claim 13. *Compare id.* at 29:43–30:10, *with id.* at 30:46–31:20. Petitioner, therefore, analyzes claim 5 using the same analysis applied to claim 13. *See* Pet. 55–57. Accordingly, at this stage of the proceeding, Petitioner has demonstrated a reasonable likelihood of showing claim 5 is unpatentable over the combination of Lisogurski and Carlson for the same reasons discussed above for claim 13.

3. Claims 7 and 15

Claim 15 depends from claim 13, and further requires the remote device to be configured to transmit at least a portion of the processed data to one or more other locations selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and to be capable of transmitting information related to a time and a position associated with the at least a portion of the processed data. Ex. 1001, 32:1–9. Claim 7 depends from

claim 5, and further adds the same limitations as claim 15. *Compare id.* at 30:15–23, *with id.* at 32:1–9.

Petitioner argues that Lisogurski's personal device or monitor 104/314 can wirelessly transmit physiological information to a central location, such as a server or workstation, which is "coupled to a network to enable the sharing of information with servers or other work stations (not shown)." *Id.* at 58–59 (citing Ex. 1011, 15:43–57, 18:11–15, 18:48–67, 20:53–60; Ex. 1003 ¶ 177). Petitioner further argues that Carlson teaches its sensor can transmit physiological data to "a special unit" worn by the user, which can generate and transmit an alarm "to a respective person, to a medical doctor, [or] to a hospital." *Id.* at 59 (citing Ex. 1009 ¶ 78; Ex. 1003 ¶ 176). Moreover, the "special unit" can include a GPS device that "at any time gives the location of the person using the pulsoximetric sensor." *Id.* (quoting Ex. 1009 ¶ 78) (emphases omitted). Petitioner argues a person skilled in the art would have found it obvious "to modify Lisogurski in the manner suggested by Carlson in order to use GPS data to track the location of a person wearing a sensor" in order to be able to "identify where the person was in case of emergency to allow any medical personnel at the central location to find the person to provide assistance." *Id.* (citing Ex. 1003 ¶ 178).

At this stage of the proceeding, Petitioner sufficiently demonstrates a reasonable likelihood of showing the combination of Lisogurski and Carlson teach all the limitations of claims 7 and 15. Lisogurski teaches monitor 104/314 "may be communicatively coupled to multi-parameter physiological monitor 326," which may itself be "coupled to a network to enable the sharing of information with servers or other workstations." Ex. 1011,

18:62–65. That is, Lisogurski teaches a remote device (a server or workstation) that transmits at least a portion of the processed data to a cloud-based server (a network server or workstation). Carlson teaches the server can be in a hospital's network or a doctor's network. Ex. 1009 ¶ 68. Carlson further teaches or suggests modifying Lisogurski's sensor 102/312 to include a GPS device to be able to communicate a monitored patient's location at any time to a monitoring hospital or doctor to enable them to provide medical assistance in the case of any emergency indicated by the physiological data transmitted to the hospital or doctor. *Id.*; *see also* Ex. 1003 ¶ 178.

4. Claims 8 and 16

Claim 16 depends from claim 13, and further requires the receiver to be located a first distance and to receive a first signal from a first one of the plurality of light emitting diodes, and to be located a different, second distance and to receive a second signal from a second one of the plurality of light emitting diodes. Ex. 1001, 32:10–15. Claim 8 depends from claim 5, and further adds the same limitations as claim 16. *Compare id.* at 30:24–30, *with id.* at 32:10–15.

Petitioner argues Lisogurski teaches using multiple light sources and detectors that "may be spaced apart" in "any suitable configuration." Pet. 60 (citing Ex. 1011, 17:39–45). Petitioner further argues because "[t]here are just two options for how two LEDs can be spaced in relation to a detector," i.e., located the same distance or different distances from the detector, a person skilled in the art "reading the indication in Lisogurski that the sensors can be spaced apart would have immediately envisioned both options." *Id.* at 61 (citing Ex. 1003 ¶ 181). Therefore, Petitioner argues, a person skilled

in the art would have understood Lisogurski to disclose spacing two LEDs at different distances from a detector as a matter of design choice, *id.* at 61 n.8, or because "a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Id.* (quoting *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)). Petitioner further argues that Lisogurski teaches a detector that detects a first signal from a first LED and a second signal from a second LED by teaching receiving signals from a red LED during a red "on" period 202 and from an IR LED during an IR "on" period 204. *Id.* at 62 (citing Ex. 1011, 7:38–8:3, 12:29–33, Figs. 2A, 2B; Ex. 1003 ¶ 183).

At this stage of the proceeding, Petitioner sufficiently demonstrates a reasonable likelihood that the combination of Lisogurski and Carlson teach the limitations of claims 8 and 16. Lisogurski discloses "[s]ensor unit 312 may include one or more light source[s] 316" and "[o]ne or more detector[s] 318." Ex. 1011, 17:37–42. Light sources 316 can include "a high efficiency infrared (IR) LED" and one or more "lower efficiency red LEDs." *Id.* at 7:58–61. The red and IR LEDs can be flashed on and off, including during separate "Red light LED 'on' periods 202" and "IR light 'on' period[s] 204," during which the signals from the red and IR LEDs can be captured by a single detector 318. *Id.* at 12:23–33, Figs. 2A, 2B.

5. Claims 9 and 17

Claim 17 depends from claim 16, and further requires the receiver's output signal to be generated in part by comparing the first and second signals. Ex. 1001, 32:16–17. Claim 9 depends from claim 8, and further adds the same limitations as claim 17. *Compare id.* at 30:31–32, *with id.* at 32:16–17.

Petitioner demonstrates, at this stage of the proceeding, how Lisogurski teaches this limitation by detecting light from red and IR LEDs pulsed at different points in a timing cycle as discussed above, and teaching that by "*comparing the intensities of two wavelengths* at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood." Pet. 62–63 (quoting Ex.1011, 4:45-51) (emphasis in original). Petitioner further demonstrates that Lisogurski computes the blood oxygen saturation from the intensities of light detected from the red and IR LEDs "using the ratio-of-ratios calculation, which is the ratio of the measured IR signal to the measured red signal." *Id.* at 63 (citing Ex. 1011, 4:45–56; Ex. 1019, 769–770; Ex. 1003 ¶ 183).

6. Claim 10

Claim 10 depends from claim 5, and further requires the output signal to include one or more physiological parameters, and the remote device to be capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time. Ex. 1001, 30:33–57.

As discussed in § II.B, *supra*, independent claim 5 is broader than independent claim 13 because it does not require the measurement device to output one or more physiological parameters and does not require the remote device to be capable of storing a history of the one or more physiological parameters over a specified period of time. *Compare id.* at 29:43–30:10, *with id.* at 30:46–31:20. Claim 10 adds these limitations to claim 5. *Id.* at 30:33–37.

Petitioner, therefore, relies on its analysis of claim 13 to teach the limitations of claim 10. *See* Pet. 63; *see also id.* at 54–55. For the reasons

explained in § II.F.2, *supra*, at this stage of the proceeding, Petitioner sufficiently demonstrates a reasonable likelihood that the combination of Lisogurski and Carlson teach the limitations of claim10.

G. Patentability of claims 8, 9, 16, and 17 over Lisogurski, Carlson, and Mannheimer

Petitioner argues claims 8, 9, 16, and 17 are unpatentable as obvious over the combination of Lisogurski, Carlson, and Mannheimer. *See* Pet. 63–69. At this stage of the proceeding, for the reasons stated below, we find Petitioner has demonstrated a reasonable likelihood of showing the unpatentability of these claims over Lisogurski, Carlson, and Mannheimer.

1. Petitioner's proposed combination

Petitioner proposes combining Lisogurski's physiological monitoring system shown in Figures 1 and 3, in which sensor 102/312 wirelessly communicates with monitor 104/314, with Carlson's teachings regarding selecting an LED pulse frequency to increase signal-to-noise in a wireless pulse oximeter sensor as discussed in § II.F.1, *supra*. We agree that a person skilled in the art would have been motivated to combine these references for the reasons discussed there.

Petitioner further proposes combining Lisogurski and Carlson with the teachings of Mannheimer. *See* Pet. 64–66. Petitioner argues that, like Lisogurski and Carlson, Mannheimer is directed to a "pulse oximetery monitoring and measurement system" that "uses one or more LEDs to alternately emit red and infrared light." *Id.* at 64 (citing Ex. 1008, 6:17–36, 6:66–7:4. Figs. 2, 4). Petitioner argues that Mannheimer teaches using "two LEDs each spaced a different distance from a single detector" so that "reflected light from a surface layer of skin . . . can be removed so that light

reflected by deeper, more vascular tissue layers can be used to identify a pulsatile signal of interest." *Id.* (citing Ex. 1008, 3:25–35, 3:38–40, 5:1–5, 5:58–62. Fig. 1B).

Petitioner argues that because Lisogurski and Carlson both teach "optimiz[ing] power consumption and increase[ing] the signal-to-noise ratio," a person skilled in the art "would have looked to other references that disclosed additional techniques for improving the operation of optical sensing systems." *Id.* at 64–65 (citing Ex. 1003 ¶ 192). Petitioner argues one reason a person skilled in the art would have looked to the teachings of Mannheimer is that Lisogurski teaches "that light is attenuated differently depending on the tissue," and Mannheimer teaches "a solution to this problem, teaching that interference from skin can be removed by using signals detected from LEDs spaced different distances from a detector." *Id.* at 65 (citing Ex. 1011, 19:42–50; Ex. 1008, 3:25–35, 5:1–5; Ex. 1003 ¶ 193).

Petitioner argues another reason a person skilled in the art would have looked to the teachings of Mannheimer is that Lisogurski teaches "using multiple light sources and multiple detectors 'which may be spaced apart,'" but does not "identify the spacing that should be used." *Id.* at 65–66 (citing Ex. 1011, 17–45, Ex. 1003 ¶ 194). Therefore, Petitioner argues, a person skilled in the art "would have looked to other prior art for guidance on how to arrange LEDs with respect to a sensor, one example of which is described in Mannheimer," which teaches "how to position emitters at different distances relative to a detector." *Id.* (citing Ex. 1003 ¶ 194).

At this stage of the proceeding, we find Petitioner has sufficiently articulated reasoning with rational underpinning for combining the teachings of Mannheimer with the teachings of Lisogurski and Carlson.

2. Claims 8 and 16

Claim 16 depends from claim 13, and further requires the receiver to be located a first distance from and to receive a first signal from a first one of the plurality of light emitting diodes, and to be located a different, second distance from and to receive a second signal from a second one of the plurality of light emitting diodes. Ex. 1001, 32:10–15. Claim 8 depends from claim 5, and further adds the same limitations as claim 16. *Compare id.* at 30:24–30, *with id.* at 32:10–15.

Petitioner sufficiently demonstrates, at this stage of the proceeding, how Mannheimer teaches this limitation by disclosing a detector 24 receiving a first signal 18 from a first LED 17 located a first distance r_1 from detector 24, and receiving a second signal 22 from a second LED 16 located a second distances r_2 from detector 24. Pet. 66–67 (citing Ex. 1008, 3:18–24, 5:58–62. Fig. 1B; Ex. 1003 ¶ 198).

Accordingly, at this stage of the proceeding, Petitioner has demonstrated a reasonable likelihood of showing claims 8 and 16 are unpatentable over the combination of Lisogurski, Carlson, and Mannheimer.

3. Claims 9 and 17

Claim 17 depends from claim 16, and further requires the receiver's output signal to be generated in part by comparing the first and second signals. Ex. 1001, 32:16–17. Claim 9 depends from claim 8, and further adds the same limitations as claim 17. *Compare id.* at 30:31–32, *with id.* at 32:16–17.

Petitioner sufficiently demonstrates, at this stage of the proceeding, how Mannheimer teaches this limitation by disclosing "calculating an arterial oxygen saturation level" related only to "the arterial blood saturation

of . . . deeper tissue" by calculating "a ratio R from I_1 and I_2," where I_1 is a first intensity "corresponding to the [first] signal 18 detected from light emitted by [first LED] E_1" and I_2 is a second intensity "corresponding to the [second] signal 20 detected from light emitted by [second LED] E_2." Pet. 68–69 (citing Ex. 1008, 2:16–18, 3:35–5:9, 5:23–57; Ex. 1003 ¶¶ 202–204).

Accordingly, at this stage of the proceeding, Petitioner has demonstrated a reasonable likelihood of showing claims 9 and 17 are unpatentable over the combination of Lisogurski, Carlson, and Mannheimer.

H. Discretionary Denial

The Director has discretion to institute *inter partes* review, and has delegated that discretion to the Board. *See* 35 U.S.C. § 314(a); *see also* 37 C.F.R. §42.4(a). When considering whether to institute *inter partes* review under § 314(a), the Board's discretion is informed by 35 U.S.C. § 316(b), which requires consideration of the effect on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability to timely complete proceedings. *See Trial Practice Guide Update*, 84 Fed. Reg. 33925, 23 (July 16, 2019).[8] Thus, the Board considers and weighs several factors in determining whether to exercise its discretion to deny institution, including whether a petitioner has filed two or more petitions against the same patent at or about the same time, and whether the petitioner has challenged the same patent in a related district court proceeding and the state of that proceeding. *See id. at 25 n.2, 26; see also NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) (precedential) ("*NHK*").

[8] Available at https://www.uspto.gov/TrialPracticeGuide3

Patent Owner argues we should deny institution under § 314(a) because the District Court in the related district court proceeding "will resolve [Petitioner's] validity arguments before any IPR trial concludes," and because "the Petition contains significant overlap with Petitioner's parallel petition in IPR2019-00913." Prelim. Resp. 4. We address each of these arguments below.

1. Related District Court Proceeding

Patent Owner filed a complaint alleging infringement of the '533 patent in the District Court for the Eastern District of Texas, and served Petitioner with the complaint on April 10, 2018. Ex. 1004, 2. The District Court issued a Scheduling Order on June 19, 2018, scheduling a dispositive motion deadline of July 9, 2019 and commencement of a jury trial on February 18, 2020. Ex. 2102, 1–2.

This Petition was filed on April 10, 2019, within the one-year time period permitted by statute. *See* 35 U.S.C. § 315(b). If the Petition is granted by the statutory deadline of October 22, 2019, a Final Written Decision will be due by October 22, 2020. *See id.* §§ 314(b), 316(a)(11). Patent Owner served Petitioner with an Amended Final Election of Asserted Claims on May 7, 2019, asserting infringement of claims 5, 9, 13, and 15–17. Ex. 2111, 1, 3. Petitioner served Patent Owner with a Final Election of Asserted Prior Art on May 22, 2019, alleging the asserted claims are invalid over, *inter alia*, Lisogurski + Carlson + Mannheimer. Ex. 2101, 2, 6.

Patent Owner argues we should exercise our discretion to deny the Petition because the Board "has found 'that the advanced state of [a]district court proceeding is an additional factor that weights in favor of denying the Petition under § 314(a),'" and "the facts here are similar to those in *NHK*."

Prelim. Resp. 4 (citing *NHK* at 20). Patent Owner argues Petitioner is challenging the validity of the '533 patent as obvious over Lisogurski, Carlson, and Mannheimer both here and in the District Court, and the District Court will determine the validity of the '533 patent using the same claim construction standard over the same prior art in February 2020, approximately eight months before we would issue a Final Written Decision in October 2020. *Id.* at 5–6 (citing *NHK* at 20).

Given these facts, we authorized Petitioner to file a Reply to Patent Owner's Preliminary Response, and Patent Owner to file a Sur-Reply, both limited to discussing the facts and factors the Board should consider when deciding whether to exercise our discretion to deny institution under § 314(a). *See* Paper 12. Petitioner filed a Reply (Paper 13, "Pet. Reply"), and Patent Owner filed a Sur-Reply (Paper 15, "PO Sur-Reply").

In its Reply, Petitioner argues that Patent Owner's request to deny institution under § 314(a) "is now moot because there will not be a trial in the Eastern District of Texas in February 2020." Pet. Reply 1. Petitioner informs us that "the Eastern District of Texas [has] granted [Petitioner's] motion to transfer the district court case to the Northern District of California," and that as a result, "all pending deadlines in the Texas action were suspended and the February 2020 trial date was vacated." *Id.* (citing Ex. 1057). Petitioner also informs us that prior to transfer of the case to the Northern District of California, "Petitioner filed a dispositive motion for invalidity for lack of written description for all asserted claims in the '533 patent," and that "[t]he case was stayed before [Patent Owner] responded to this motion." *Id.* at 6–7. Moreover, Petitioner informs us that it did not file any "dispositive motions involv[ing] invalidity based on prior art" in the

district court proceeding. *Id.* at 6. Petitioner also argues that because its "challenges in the district court action include . . . the prior art used in the grounds of the Petition," we should institute this proceeding on the merits because doing so "would simplify and narrow the dispute in district court." *Id.* at 4.

Patent Owner, in its Sur-Reply, does not dispute Petitioner's contention that the only dispositive motion Petitioner filed in the district court proceeding challenged the validity of the '533 patent on the grounds of lack of written description, and that Petitioner did not file any dispositive motions challenging validity on the grounds of obviousness over prior art. PO Sur-Reply 7. Patent Owner also does not dispute that the district court case has been transferred to the Northern District of California, and stayed pending that transfer. *Id.* at 1. However, Patent Owner argues that transfer was completed on October 2, 2019 and that "the stay was lifted upon completion of the transfer." *Id.* at 1 (citing Ex. 1057, 1; Ex. 2113, 33). Nonetheless, Patent Owner admits that although "[t]he parties have filed opening summary judgment briefs," the assigned Judge in the Northern District of California "has not yet set a schedule for the remaining briefs or a trial date." *Id.* at 2. Still, Patent Owner argues that because the assigned Judge scheduled trial 3.5 months "after the deadline for summary judgement response briefs" in a different patent case, "it is likely that trial will be completed in the second quarter of 2020 and certainly no later than June 2020." *Id.* at 2–3.

Upon consideration of the evidence and arguments presented, we are not persuaded that we should exercise our discretion to deny institution under § 314(a). The related district court proceeding has been transferred

from the Eastern District of Texas to the Northern District of California, mooting the February 2020 trial date in the Eastern District of Texas. Ex. 1057, 1. Petitioner has not filed any dispositive motions challenging the validity of the '533 patent on any prior art grounds. Pet. Reply 6–7; PO Sur-Reply 7; Ex. 1057, 1–3. Therefore, the validity of the claims challenged in the Petition over the art raised in the Petition will not be determined in the related district court proceeding until a jury makes that determination after a trial on the merits in the Northern District of California.

To date, as Patent Owner admits, no scheduling order has issued for the Northern District of California proceeding, and no trial date has been set. PO Sur-Reply 2. Although Patent Owner asserts that the Northern District of California proceeding is *likely* to go to trial "in the second quarter of 2020 and certainly no later than June 2020," Patent Owner's assertion, given the facts described above, is speculation. We decline to engage in such speculation to determine whether to proceed with an *inter partes* review in this Proceeding.

Accordingly, for the reasons discussed above, we decline to exercise our discretion to deny institution under 35 U.S.C. § 314(a) due to the pending litigation in the Northern District of California.

2. Related Inter Partes Review Proceeding

In this Proceeding, Petitioner challenges claims 5, 7–10, 13, and 15–17 as unpatentable over Lisogurski and Carlson, and claims 8, 9, 16, and 17 as unpatentable over Lisogurski, Carlson, and Mannheimer. Pet. 3. In *Apple Inc. v. Omni MedSci Inc.*, IPR2019-00913 (PTAB), Petitioner challenges

claims 5, 7–10, 13, and 15–17 as unpatentable over Valencell 093[9] and Valencell 099[10], with or without Carlson, and claims 8, 9, 16, and 17 as unpatentable over Valencell 093, Valencell 099, and Mannheimer, with or without Carlson. IPR2019-00913, Paper 1, 4.

Patent Owner argues we should exercise our discretion to deny institution of this Proceeding because "Petitioner filed parallel and substantially overlapping IPR petitions against the '533 patent but has not identified any material differences between them." Prelim. Resp. 6 (citing *Comcast Cable Comms. v. Rovi Guides, Inc.*, IPR2019-00232, slip op. at 12–13 (PTAB May 20, 2019) (Paper 14); *Trial Practice Guide Update* (July 15, 2019); 84 Fed. Reg. 33925). Patent Owner argues that in IPR2019-00913, Petitioner "challenge[s] the same claims as in this Petition, but merely replace[s] Lisogurski" with the combination of Valencell 093 and Valencell 099, without explaining "any material differences" between these references. *Id.* at 7–8. Patent Owner argues that by "present[ing] six different grounds challenging the same claims without identifying any material differences in the references, Petitioner seeks review of redundant arguments, contrary to the purpose of IPR and the directive to ensure efficient use of the Board's resources." *Id.* at 9 (citing 35 U.S.C. § 314(a)).

We are not persuaded by Patent Owner's arguments, and decline to deny institution of the Petition under 35 U.S.C. § 314(a) due to the related petition filed in IPR2019-00913. In doing so, we are mindful of the following facts: (a) this Petition was filed on April 10, 2019 (Paper 3, 1),

[9] U.S. Patent Publication No. 2012/0197093 A1.

[10] U.S. Patent Publication No. 2010/0217099 A1.

(b) the *Comcast* Decision issued on May 20, 2019, and (3) the latest Trial Practice Update was published on July 15, 2019. Thus, when the Petition was filed, Petitioner was not aware of the Board's guidance that, *subsequent* to the publication of the July 2019 Trial Practice Guide Update:

> If a petitioner files two or more petitions challenging the same patent, then the petitioner should, in its petitions or in a separate paper filed with the petitions, identify (1) a ranking of the petitions in the order it wishes the Board to consider the merits, if the Board uses its discretion to institute any of the petitions, and (2) a succinct explanation of the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute additional petitions if it identifies one petition that satisfies petitioner's burden under 35 U.S.C. § 314(a).

Trial Practice Guide Update (July 2019), 27; *see also id.* at 27 n.4 ("*After the publication of this guide*, it will be expected that petitioners will justify multiple petitions in the first instance in their petitions or in a separate paper with the petitions.") (emphasis added). For petitions filed prior to publication of the July 2019 Trial Practice Guide Update, the Board has discretion to authorize a petitioner to file a paper justifying the need to file two or more petitions. *Id.* at 27 n.4 ("Prior to the issuance of this guide, a panel requested from the petitioner . . . an additional paper . . . to address these issues. Panels *may* continue to authorize such papers for *petitions submitted before* the publication of this guide.") (emphases added).

Although not expressly stated in the July 2019 Trial Practice Guide Update, the guidance provided suggests that the reason a petitioner should rank its petitions and identify the differences between them is to facilitate the Board's consideration of "why the Board should exercise its discretion to institute additional petitions *if it identifies one petition that satisfies*

petitioner's burden under 35 U.S.C. § 314(a)." *Id.* at 27 (emphasis added); *see also Comcast*, slip op. at 8 (Paper 14) ("in light of the specific facts of this case, we exercise our discretion to deny institution of the present Petition under § 314(a) in light of IPR2019-00231, *which we are instituting*.") (emphasis added).

Here, in addition to not authorizing Petitioner to file a paper ranking and explaining the differences between this Petition and the petition filed in IPR2019-00913, we have denied the petition filed in IPR2019-00913 on the merits. *See Apple Inc. v. Omni MedSci, Inc.*, IPR2019-00913, Paper 14 at 24 (PTAB Oct. 16, 2019). Thus, only this Petition will proceed on the merits, and Patent Owner's burden will be limited to defending the patentability of the claims challenged on the grounds raised in this Petition. These facts alleviate the concerns, also expressed in the July 2019 Trial Practice Guide Update, of "plac[ing] a substantial and unnecessary burden on the Board and the patent owner" and of raising "fairness, timing, and efficiency concerns." Trial Practice Guide Update (July 15, 2019), 26.

Accordingly, for the reasons discussed above, we decline to exercise our discretion to deny this Petition under 35 U.S.C. § 314(a) due to Petitioner's filing of a concurrent petition challenging the same claims of the '533 patent on different grounds in IPR2019-00913.

III. CONCLUSION

We have reviewed the Petition and Preliminary Response, and have considered all of the evidence and arguments presented by Petitioner and Patent Owner. We find, on this record, Petitioner has demonstrated a reasonable likelihood of showing claims 5, 7–10, 13, and 15–17 of the '533

patent are unpatentable. Accordingly, we institute *inter partes* review of all claims on all grounds raised in the Petition.

The Board has not yet made a final determination with respect to any claim construction issue or the patentability of any challenged claim.

IV. ORDER

It is ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted on all challenged claims on all grounds; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

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Paper No. 39
Date: October 14, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Case IPR2019-00916
Patent 9,651,533 B2

Before GRACE KARAFFA OBERMANN, JOHN F. HORVATH, and SHARON FENICK, *Administrative Patent Judges.*

PER CURIAM

Opinion Concurring filed by *Administrative Patent Judge* HORVATH

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

Apple Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 5, 7–10, 13, and 15–17 ("the challenged claims") of U.S. Patent No. 9,651,533 B2 (Ex. 1001, "the '533 patent"). Paper 1 ("Pet."), 3. Omni MedSci Inc. ("Patent Owner"), filed a Preliminary Response. Paper 10 ("Prelim. Resp."). Upon consideration of the Petition and Preliminary Response, we instituted *inter partes* review of all challenged claims on all grounds raised. Paper 16 ("Dec. Inst.").

Patent Owner filed a Response to the Petition (Paper 23, "PO Resp."), Petitioner filed a Reply (Paper 28, "Pet. Reply"), and Patent Owner filed a Sur-Reply (Paper 32, "PO Sur-Reply"). An oral hearing was held on July 16, 2020, and the hearing transcript is included in the record. *See* Paper 37 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we find Petitioner has shown by a preponderance of evidence that claims 5, 7–10, 13, and 15–17 of the '533 patent are unpatentable.

B. Related Matters

Petitioner and Patent Owner identify the following as matters that can affect or be affected by this proceeding: pending U.S. Patent Application Nos. 10/188,299, 10/172,523, 15/594,053, 16/015,737, and 16/241,628; *Apple Inc. v. Omni MedSci Inc.*, IPR2019-00913 (PTAB); and *Omni MedSci*

Inc. v. Apple Inc., 2-18-cv-00134-RWD (E.D. Tex.).[1] *See* Pet. x; Paper 7, 1–2.

C. Evidence Relied Upon[2]

Reference		Date	Exhibit
Mannheimer	U.S. 5,746,206	May 5, 1998	1008
Carlson	U.S. 2005/0049468 A1	Mar. 3, 2005	1009
Lisogurski	U.S. 9,241,676 B2	May 31, 2012[3]	1011

D. Instituted Grounds of Unpatentability

Claims Challenged	Basis	References
5, 7–10, 13, and 15–17	§ 103(a)	Lisogurski and Carlson
8, 9, 16, and 17	§ 103(a)	Lisogurski, Carlson, and Mannheimer

II. ANALYSIS

A. The '533 Patent

The '533 patent was filed on October 6, 2015, and claims priority to a utility application filed on December 17, 2013, and a provisional application filed on December 31, 2012. Ex. 1001, codes (22), (60), (63), 1:10–14. The '533 patent is directed toward a wearable physiological measurement

[1] This case was transferred to the Northern District of California. *See* Paper 11, 1; Paper 13, 1; Ex. 1058, 9.

[2] Petitioner also relies upon the Declaration of Brian Anthony, Ph.D., (Ex. 1003).

[3] Petitioner relies on the filing date of Lisogurski to establish its status as prior art. *See* Pet. 21.

system. *Id.* code (57). The system is depicted in Figure 24 of the '533 patent, which is reproduced below.

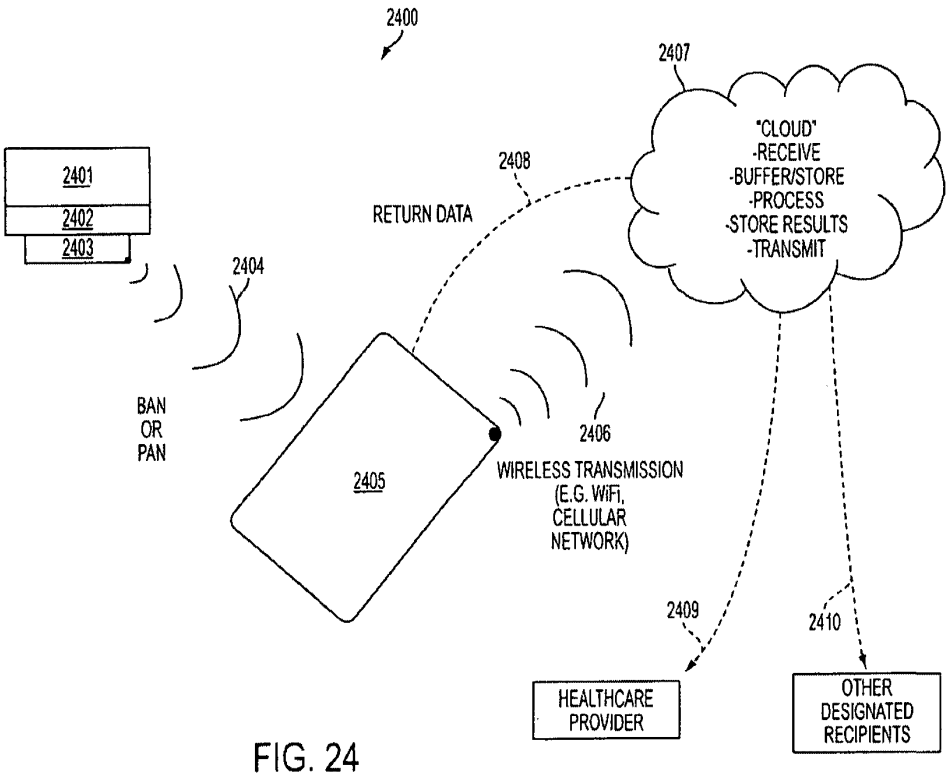


FIG. 24

Figure 24 is a schematic illustration of a physiological measurement system that includes wearable measurement device 2401, personal device 2405, and cloud based server 2407. *Id.* at 7:7–10, 26:49–27:20.

The "wearable measurement device [is] for measuring one or more physiological parameters." *Id.* at 5:35–37. A schematic illustration of such a device is shown in Figure 18 of the '533 patent, which is reproduced below.

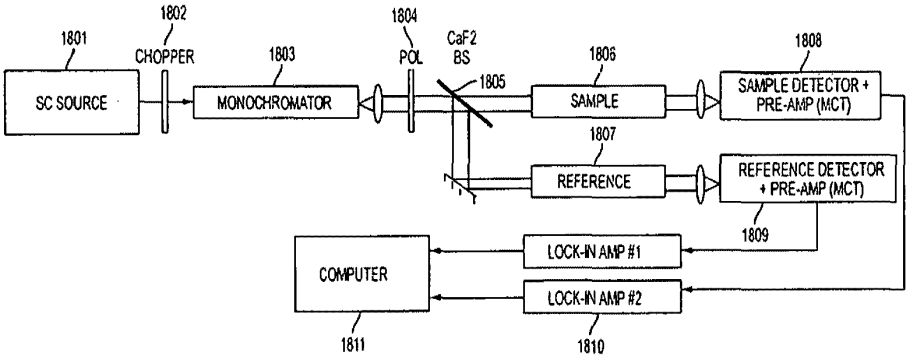


FIG. 18

Figure 18 is a schematic diagram of a wearable physiological measurement device to "subtract out (or at least minimize the adverse effects of) light source fluctuations." *Id.* at 18:43–46. The device includes light source 1801 made from a plurality of light emitting diodes that output an optical beam at one or more wavelengths, including at least one wavelength between 700 and 2500 nanometers. *Id.* at 5:37–43, 18:46–48. The device includes a plurality of lenses that receive a portion of the output optical beam from the light source and deliver an analysis beam to a sample. *Id.* at 5:47–50, 18:46–55. The device includes a receiver that receives at least a portion of the analysis beam that has been reflected from or transmitted through the sample, and processes that signal to generate an output signal. *Id.* at 5:51–54, 18:55–59.

Light source 1801 "is configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources [e.g., LEDs] and by increasing a pulse rate of at least one of the plurality of semiconductor sources." *Id.* at 5:43–47. For example, light source 1801 can be "an active illuminator" that allows "higher signal-

to-noise ratios [to] be achieved." *Id.* at 16:54–58. This can be done, for example, "us[ing] modulation and lock-in techniques" in which the "light source may be modulated, and then the detection system [is] synchronized with the light source." *Id.* at 16:58–62. "[N]arrow band filtering around the modulation frequency may be used to reject noise outside the modulation frequency." *Id.* at 16:64–65.

The physiological measurement system also includes personal device 2405 having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen. *Id.* at 5:54–59, 27:3–7. Personal device 2405 receives and processes at least a portion of the output signal generated by wearable measurement device 2401, and stores and displays the processed output signal. *Id.* at 5:59–61, 27:10–12. Personal device 2405 also transmits at least a portion of the processed output signal over a wireless transmission link to a remote device such as an internet or "cloud" based server. *Id.* at 5:61–63, 26:30–34, 27:12–15. Personal device 2405 can be "a smart phone, tablet, cell phone, PDA, or computer," or some "other microprocessor-based device." *Id.* at 26:37–40, 26:49–55.

The physiological measurement system also includes remote device 2407 that receives the portion of the processed output signal transmitted by personal device 2405 as an output status. *Id.* at 5:63–66, 26:30–42, 27:12–15. Remote device 2407 processes the output status to generate and store processed data, and stores a history of the output status over a period of time. *Id.* at 5:66–6:1–3, 27:21–29, 27:34–37.

B. Illustrative Claim

Claim 13 of the '533 patent is an independent and representative claim, and is reproduced below.

> 13. A measurement system comprising:
>
> a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,
>
> the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;
>
> the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample;
>
> the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the wearable measurement device receiver is configured to be synchronized to pulses of the light source;
>
> a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a

> microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and
>
> a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data and wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.

Ex. 1001, 30:46–31:20.

Claim 5 is an independent claim that recites a measurement system that is substantially similar to the measurement system recited in claim 13, except that claim 5 is broader because it does not require (a) the light source, plurality of lenses, and receiver to be components of a wearable measurement device, (b) measurement of one or more physiological parameters, or (c) the remote device to be capable of storing a history of at least a portion of the received output status over a specified period of time. *Compare id.* at 29:43–30:10, *with id.* at 30:46–31:20. Claims 7–10 depend from claim 5, and claims 15–17 depend from claim 13. *Id.* at 30:15–37, 32:1–18.

C. Level of Ordinary Skill in the Art

Petitioner, relying on the testimony of Dr. Anthony, identifies a person of ordinary skill in the art ("POSITA") as someone who "would have

[had] a good working knowledge of optical sensing techniques and their applications, and familiarity with optical system design and signal processing techniques." Pet. 16; Ex. 1003 ¶ 35. Such a person would have obtained such knowledge through "an undergraduate education in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with relevant experience studying or developing physiological monitoring devices . . . in industry or academia." *Id.* Patent Owner does not dispute this. *See* PO Resp. 8.

We find Petitioner's undisputed definition of the person of ordinary skill in the art to be consistent with the problems and solutions disclosed in the patent and prior art of record, and adopt it as our own. *See, e.g.*, *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

D. Claim Construction

In *inter partes* reviews, we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Only claim terms which are in controversy need to be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

1. Beam, plurality of lenses, pulse rate

Petitioner requests construction of the terms "beam," "plurality of lenses," and "pulse rate." *See* Pet. 18–20. We declined to expressly construe these terms in our Institution Decision because their construction

was not needed to resolve any dispute between the parties. *See* Dec. Inst. 9. Neither party disputes that initial determination, which we maintain here. *See* PO Resp. 8–13; Pet. Reply 2–9.

2. Personal device

We expressly construed this term in our Institution Decision to resolve a dispute between the parties. *See* Dec. Inst. 11–12. Specifically, we construed the term to include, but not be limited to, "a computer or microprocessor-based device having a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor, and a touch screen." *Id.* Neither party disputes that construction, which we maintain here. *See* PO Resp. 8–13; Pet. Reply 2–9.

3. Light source

In our Institution Decision, we expressly construed "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources." Dec. Inst. 9–11. In doing so, we noted the scant support for this term in the Specification, which twice repeats the same phrase with no explanation of its meaning. *Id.* at 10. We further noted the Specification and claims were amended at the same time to include this phrase, with no indication of how the phrase was supported by the originally filed Specification. *Id.* at 10, n.4. Nonetheless, we construed the phrase to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes is capable of having its pulse rate increased to increase a signal-to-noise ratio." *Id.* at 10.

Patent Owner disputes this construction, arguing it "eliminat[es] the claimed 'actor' that increases the pulse rate, *i.e.*, the device," and erroneously "replaces the claim term 'configured to' with the broader phrase 'is capable of.'" PO Resp. 9. Patent Owner argues the correct construction of this term is "a light source, containing two or more light emitting diodes (semiconductor sources), where the light source is configured to increase the pulse rate of at least one of the light emitting diodes to increase signal-to-noise ratio."[4] *Id.* at 13. Patent Owner argues the Specification supports this construction by disclosing "'use of an active illuminator, [whereby] a number of advantages may be achieved' including 'high signal-to-noise ratios.'" *Id.* at 12 (quoting Ex. 1001, 16:54–58).

We are not persuaded by Patent Owner's arguments. First, the limitation does not recite a "device" or "actor" configured to increase signal-to-noise by increasing LED pulse rate. Instead, it recites a "light source comprising a plurality of . . . light emitting diodes," where the light source itself—i.e., the plurality of LEDs—is "configured to increase signal-to-noise ratio by increasing . . . a pulse rate of at least one of the plurality of [LEDs]." Ex. 1001, 16:48–50, 16:56–60. That is, the limitation recites a plurality of LEDs that are configured to increase signal-to-noise by increasing the pulse rate of at least one of the LEDs. No "device" or "actor" is recited to increase the pulse rate of the LEDs. Thus, the only reasonable construction is that the

[4] We note here that Patent Owner contradicts this proposed construction in its Sur-Reply, where Patent Owner argues "[t]he claim requires a light source 'configured to increase SNR,' not a light source 'configured to increase a pulse rate.'" PO Sur-Reply 4.

LEDs are "capable" of having their pulse rate increased to increase signal-to-noise, as we initially construed this phrase.

Patent Owner argues that our construction is incorrect because "capable of" is a broader term than "configured to" and, therefore, "configured to" does not mean "capable of." PO Resp. 10 (citing *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012)). In the context of these claims, we disagree. First, we note that *Aspex Eyewear* did not consider and did not construe "configured to." *See Aspex Eyewear,* 672 F.3d at 1348–49. Instead, the term "magnetic members *adapted to* extend" was construed to mean "magnetic members . . . *made to* extend." *Id.* at 1348 (emphases added). By contrast, the proper construction of "configured to" was considered in *Superior Industries, Inc. v. Masaba, Inc.*, 650 Fed. App'x. 994 (Fed. Cir. 2016). In *Superior Industries*, the Federal Circuit considered and approved a district court's construction of a "support frame . . . *configured to* support an end of an earthen ramp" to mean "the support frame be *capable of* supporting an earthen ramp." *Id.* at 996, 998 (emphases added).

Accordingly, for these reasons, we maintain our construction of this limitation to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes is capable of having its pulse rate increased to increase a signal-to-noise ratio."

E. Overview of the Prior Art

1. Lisogurski

Lisogurski discloses a "physiological monitoring system [that] monitor[s] one or more physiological parameters of a patient . . . using one

or more physiological sensors." Ex. 1011, 3:44–46. The physiological sensors may include a "pulse oximeter [that] non-invasively measure[s] the oxygen saturation of a patient's blood." *Id.* at 3:62–64. The pulse oximeter includes "a light sensor that is placed at a site on a patient, typically a fingertip, toe, forehead, or earlobe." *Id.* at 4:6–7. The light sensor "pass[es] light through blood perfused tissue and photoelectrically sense[s] the absorption of the light in the tissue." *Id.* at 4:8–11. The light sensor emits "one or more wavelengths [of light] that are attenuated by the blood in an amount representative of the blood constituent concentration," including red and infrared (IR) wavelengths of light. *Id.* at 4:42–48.

Figure 3 of Lisogurski is reproduced below.

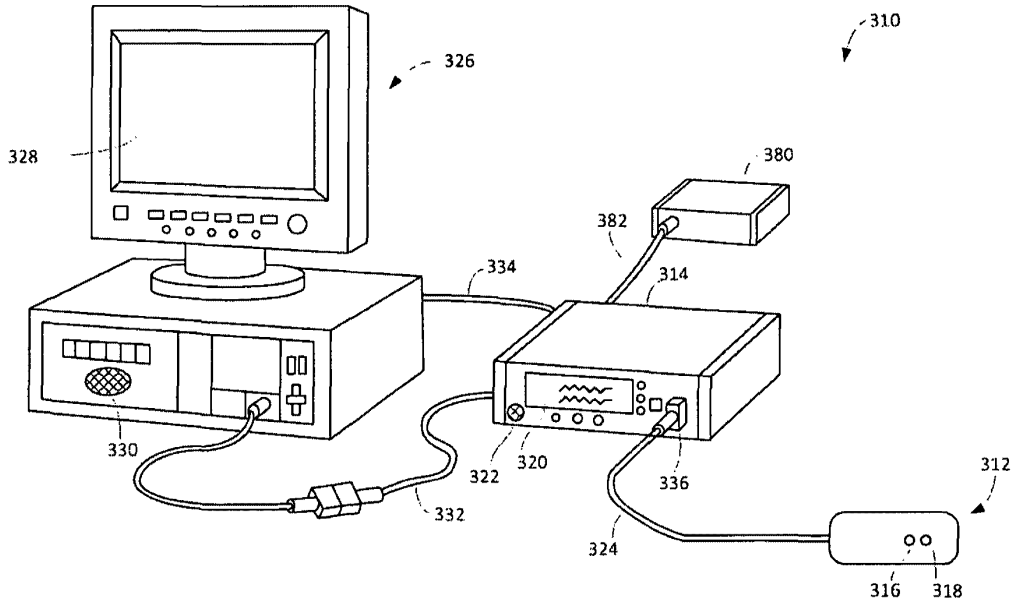


FIG. 3

Figure 3 of Lisogurski is "a perspective view of an embodiment of a physiological monitoring system." *Id.* at 2:23–25. The system includes

sensor 312, monitor 314, and multi-parameter physiological monitor ("MPPM") 326. *Id.* at 17:35–36, 18:44–45. Sensor 312 includes "one or more light sources 316 for emitting light at one or more wavelengths" and detector 318 for "detecting the light that is reflected by or has traveled through the subject's tissue." *Id.* at 17:37–42. Sensor 312 may have "[a]ny suitable configuration of light source 316 and detector 318," and "may include multiple light sources and detectors [that] may be spaced apart." *Id.* at 17:42–45. Light source 316 may include "LEDs of multiple wavelengths, for example a red LED and an IR [LED]." *Id.* at 19:25–27. Sensor 312 may be "wirelessly connected to monitor 314." *Id.* at 17:57–59.

Monitor 314 "calculate[s] physiological parameters based at least in part on data relating to light emission . . . received from one or more sensor units such as sensor unit 312." *Id.* at 17:59–62. Monitor 314 includes "display 320 . . . to display the physiological parameters," and "speaker 322 to provide an audible . . . alarm in the event that a subject's physiological parameters are not within a predefined normal range." *Id.* at 18:3–10. Monitor 314 is communicatively coupled to MPPM 326, with which it "may communicate wirelessly." *Id.* at 18:58–61. Monitor 314 may also be "coupled to a network to enable the sharing of information with servers or other workstations." *Id.* at 18:62–65.

MPPM 326 may "calculate physiological parameters and . . . provide a display 328 for information from monitor 314." *Id.* at 18:49–52. MPPM 326 may also be "coupled to a network to enable the sharing of information with servers or other workstations." *Id.* at 18:62–65. The remote network servers may "be used to determine physiological parameters," and may display the parameters on a remote display, display 320 of monitor 314, or

display 328 of MPPM 326. *Id.* at 20:53–58. The remote servers may also "publish the data to a server or website," or otherwise "make the parameters available to a user." *Id.* at 20:58–60.

Lisogurski discloses the monitoring system shown in Figure 3, described above, "may include one or more components of physiological monitoring system 100 of FIG. 1." *Id.* at 17:32–35. Lisogurski further discloses that although "the components of physiological monitoring system 100 . . . are shown and described as separate components. . . . the functionality of some of the components may be combined in a single component," and "the functionality of some of the components . . . may be divided over multiple components." *Id.* at 15:66–16:9. Figure 1 of Lisogurski is reproduced below.

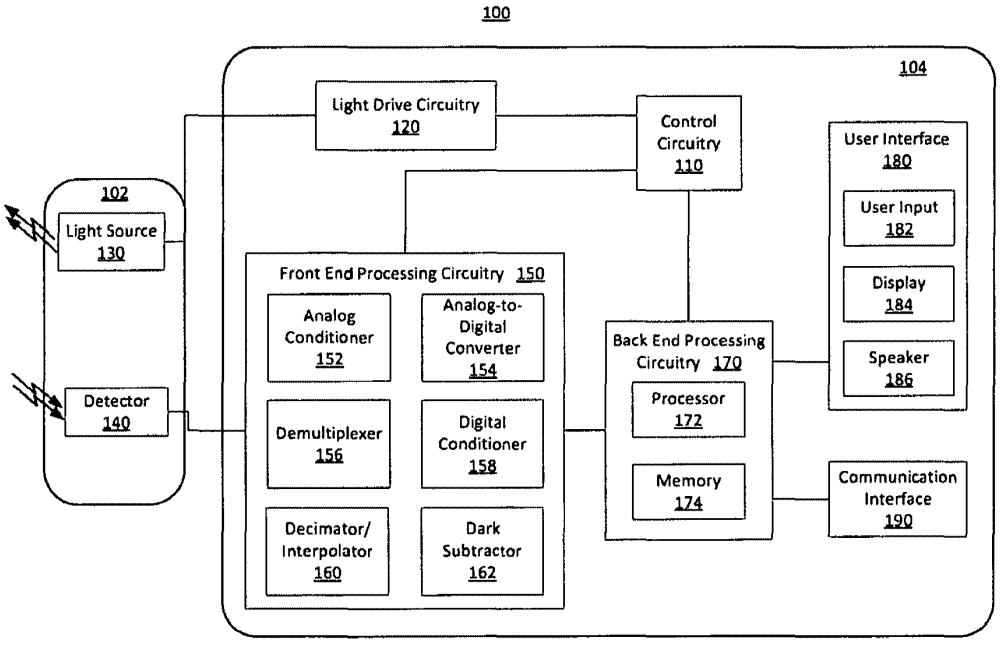


FIG. 1

Figure 1 of Lisogurski is a "block diagram of an illustrative physiological monitoring system." *Id.* at 2:11–13. The system includes "sensor 102 and monitor 104 for generating and processing physiological signals of a subject." *Id.* at 10:44–46. Sensor 102 includes "light source 130 and detector 140." *Id.* at 10:48–49. Light source 130 includes "a Red light emitting light source and an IR light emitting light source," such as Red and IR emitting LEDs, with the IR LED emitting light with a "wavelength [that] may be between about 800 nm and 1000 nm." *Id.* at 10:52–58. Detector 140 "detect[s] the intensity of light at the Red and IR wavelengths," converts them to an electrical signal, and "send[s] the detection signal to monitor 104, where the detection signal may be processed and physiological parameters may be determined." *Id.* at 11:9–10, 11:20–23.

Monitor 104 includes user interface 180, communication interface 190, and control circuitry 110 for controlling (a) light drive circuitry 120, (b) front end processing circuitry 150, and (c) back end processing circuitry 170 via "timing control signals." *Id.* at 11:33–38, Fig. 1. Light drive circuitry 120 "generate[s] a light drive signal . . . used to turn on and off the light source 130, based on the timing control signals." *Id.* at 11:38–40. The light drive signal "control[s] the intensity of light source 130 and the timing of when the light source 130 is turned on and off." *Id.* at 11:50–54. Front end processing circuitry 150 "receive[s] a detection signal from detector 140 and provides one or more processed signals to back end processing circuitry 170." *Id.* at 12:42–45. Front end processing circuitry 150 "synchronize[s] the operation of an analog-to-digital converter and a demultiplexer with the light drive signal based on the timing control signals." *Id.* at 11:43–46.

Backend processing circuitry 170 "use[s] the timing control signals to coordinate its operation with front end processing circuitry 150." *Id.* at 11:46–49. Backend processing circuitry 170 includes processor 172 and memory 174, and "receive[s] and process[es] physiological signals received from front end processing circuitry 150" to "determine one or more physiological parameters." *Id.* at 14:56–57, 14:60–64. Backend processing circuitry 170 is "communicatively coupled [to] use[r] interface 180 and communication interface 190." *Id.* at 15:16–18. User interface 180 includes "user input 182, display 184, and speaker 186," and may include "a keyboard, a mouse, a touch screen, buttons, switches, [and] a microphone." *Id.* at 15:19–22. Communication interface 190 allows "monitor 104 to exchange information with external devices," and includes transmitters and receivers to allow wireless communications. *Id.* at 15:43–44, 15:48–57.

Lisogurski teaches the physiological monitoring system may modulate the light drive signal to have a "period the same as or closely related to the period of [a] cardiac cycle." *Id.* at 25:49–51. Thus, "[t]he system may vary parameters related to the light drive signal including drive current or light brightness, duty cycle, firing rate, . . . [and] other suitable parameters." *Id.* at 25:52–55. Lisogurski further teaches "the system may alter the cardiac cycle modulation technique based on the level of noise, ambient light, [and] other suitable reasons." *Id.* at 9:46–48. Thus, "[t]he system may increase the brightness of the light sources in response to [any] noise to improve the signal-to-noise ratio." *Id.* at 9:50–52. The system may also "change from a modulated light output to a constant light output in response to noise, patient motion, or ambient light." *Id.* at 9:57–60.

2. Carlson

Carlson discloses an "optical pulsoximetry [device] used for non-invasive measurement of pulsation and oxygen saturation in arterial human or animal blood." Ex. 1009 ¶ 2. The device measures the light "absorption of reduced (Hb)—and oxidized (HbO_2) h[e]moglobin at two optical wavelengths, where the relative absorption coefficients differ significantly." *Id.* ¶ 3.

Figure 2 of Carlson is reproduced below.

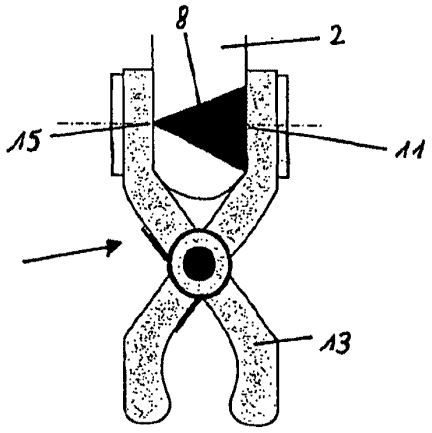


Figure 2

Figure 2 of Carlson is a schematic illustration of an ear clip sensor 1 of a pulsoximeter device. *Id.* ¶¶ 33, 49. Sensor 1 includes light source 15, which transmits light beam 8 through a patient's earlobe 2, and light detector 11 to detect the transmitted light. *Id.* ¶ 49. Light source 15 emits light at two wavelengths—660 nm and 890 nm—and can consist of two LEDs. *Id.* ¶ 50.

Carlson's pulsoximeter can be used to "survey the health condition of a person or an animal [that] is mobile." *Id.* ¶ 72. Carlson teaches that patient mobility can cause "standard pulsoximeter sensors [to] suffer from

signal instability and insufficient robustness versus environmental disturbances." *Id.* ¶ 4. Environmental disturbances can include ambient light, such as sunlight. *Id.* ¶ 68. For example, a person walking or driving down a tree-lined avenue can experience "relatively quick changing conditions between sunlight and shadow," such that a pulsoximeter sensor worn by the person will receive sunlight "at a certain frequency, which means that every time when passing a tree, sunlight is attenuated and between the trees sunlight is influencing the measurement of the pulsoximeter sensor." *Id.*

To address such problems, Carlson includes "optical and/or electronic means for increasing Signal-to-Noise ratio (S/N) . . . in rough (optical) environmental conditions." *Id.* ¶ 10. In particular, Carlson's LEDs emit light "not as a current or continuous light but as pulsed light." *Id.* ¶ 69. Carlson "temporarily modulate[s] the optical radiation of the LED at the carrier frequency f_0 in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶ 65. Temporary modulation frequency f_0 is "chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light." *Id.* ¶ 69. This allows easy discrimination of pulsoximeter signals from environmental signals, such as sunlight and ambient light, and "increas[es] significantly the Signal-to-Noise and Signal-to-Background ratio." *Id.*

Carlson further discloses that sensor 1 can be wirelessly connected to "a special unit worn by [a] person or patient," where "a signal is generated if [a] measured value is not within a predetermined range." *Id.* ¶¶ 77–78. The generated signal can be "transmitted to a respective person, to a medical

doctor, to a hospital, etc." *Id.* ¶ 78. The pulsoximeter can also include a "GPS device which at any time gives the location of the person using the pulsoximetric sensor monitoring configuration." *Id.*

3. Mannheimer

Mannheimer discloses a pulse oximetry device that "non-invasively measure[s] oxygen saturation of arterial blood in vivo." Ex. 1008, 1:10–13. Mannheimer's device performs a "pulsed oximetry measurement [that] isolates arterial saturation levels for particular ranges of tissue layers . . . by utilizing multiple spaced detectors and/or emitters." *Id.* at 2:1–6. Figure 1A of Mannheimer is reproduced below.

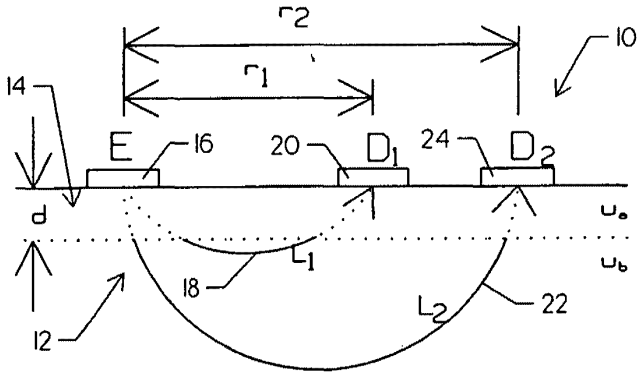


FIG. 1 A

Figure 1A of Mannheimer is a schematic diagram of a first embodiment of a pulse oximeter having one emitter 16 and two detectors 20/24. *Id.* at 2:40–42. Emitter 16 can be a single LED or multiple LEDs collocated to simulate a single point source. *Id.* at 3:13–18. Emitter 16 is separated from detector 20 by a first distance r_1, and is separated from detector 24 by a second distance r_2. *Id.* at 3:23–24. Light from emitter 16 is scattered by skin layer 14 and deeper skin layer 12, and reaches detectors 20/24 via respective paths

18/22. *Id.* at 3:18–20. Mannheimer calculates blood oxygen concentration in skin layer 12 from the intensity of two different wavelengths of light detected at detectors 20/24 at two different times. *Id.* at 3:35–4:63.

In addition to the embodiment shown in Figure 1A, Mannheimer discloses a second embodiment of a pulse oximeter in Figure 1B, reproduced below.

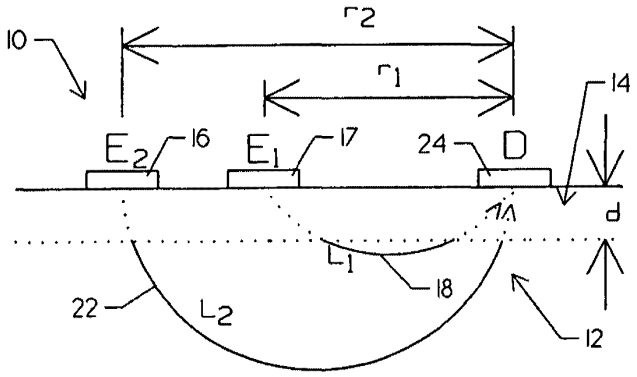


FIG. 1 B

Figure 1B of Mannheimer is a schematic diagram of a second embodiment of a pulse oximeter having two emitters 16/17 and one detector 24. *Id.* at 2:43–44, 3:37–39. As shown in Figure 1B, emitter 17 is separated from detector 24 by a first distance r_1, and emitter 16 is separated from detector 24 by a second distance r_2. Mannheimer discloses that "[t]hose of skill in the art will appreciate that the operation" of the second embodiment shown in Figure 1B "is similar to that described above" in reference to the first embodiment shown in Figure 1A. *Id.* at 5:58–62.

F. Patentability of claims 5, 7–10, 13, and 15–17 over Lisogurski and Carlson

Petitioner argues claims 5, 7–10, 13, and 15–17 are unpatentable as obvious over the combination of Lisogurski and Carlson. *See* Pet. 21–63.

1. Petitioner's proposed combination

Petitioner proposes combining Lisogurski's physiological monitoring system shown in Figures 1 and 3, in which sensor 102/312 wirelessly communicates with monitor 104/314, with Carlson's teachings regarding pulsing an LED at a frequency that increases signal-to-noise in a wireless pulsoximeter sensor. *See* Pet. 24–26, 32–34, 38–39, 41–44, 47–51.

Petitioner's proposed combination relocates some components of Lisogurski's monitor 104/314 to sensor 102/312, as illustrated in a series of Petitioner-modified versions of Lisogurski's Figure 1, which we combine into a single modified version shown below. *See id.* at 33, 47, 50.

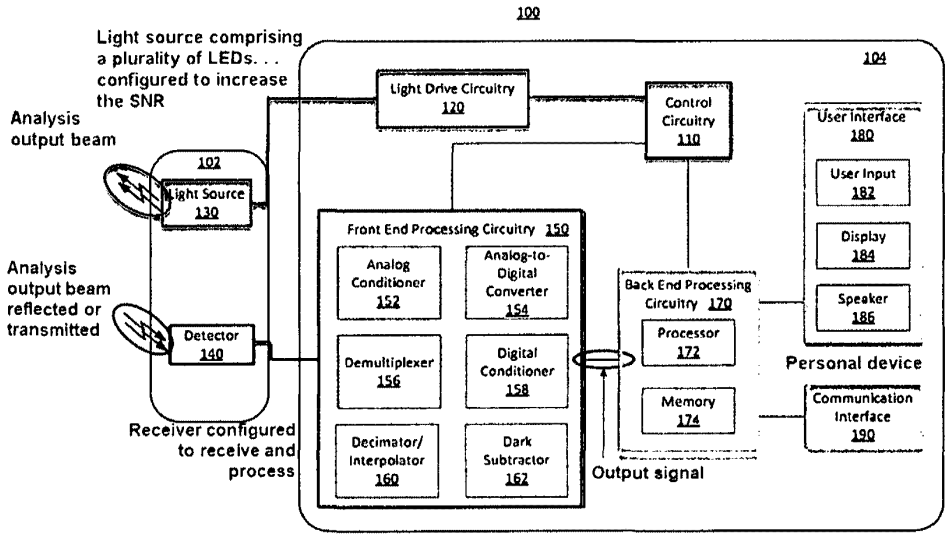


FIG. 1

Modified Figure 1 of Lisogurski illustrates Petitioner's proposed combination, which involves relocating control circuitry 110, light drive circuitry 120, and front end processing circuitry 150 of monitor 104 to sensor 102 as illustrated. *Id.*

Petitioner articulates sufficient reasoning with rational underpinning to demonstrate why a person of ordinary skill in the art would have modified Lisogurski's sensor 102/312 and monitor 104/314 in the manner proposed. *See id.* at 6–12, 32–34, 47–49 (citing/quoting Ex. 1003 ¶¶ 48–56, 98–103, 138, 142–146; Ex. 1005 ¶ 3; Ex. 1009 ¶ 4; Ex. 1011, 11:20–27, 11:38–41, 11:5054, 16:2–9, 17:32–35, 17:55–59, 18:16–31, 25:52–55; Ex. 1020, 3, 6–7, 12; Ex. 1021, 2–4; Ex. 1022, 1; Ex. 1023, 1, 2, 5, 6; Ex. 1024, 459, 460, 462; Ex. 1027, 9, 10, 15–31, 33, 35, 40–49; Ex. 1029, 221).

First, Lisogurski expressly suggests the modification by teaching embodiments in which "the functionality of some of the components may be combined in a single component" and embodiments in which "the functionality of some of the components of monitor 104 . . . may be divided over multiple components." Ex. 1011, 16:2–4, 16:7–9. Second, numerous industry trends motivate the modification. These include improving the capabilities of wearable sensors for use in sports and personal fitness applications and wirelessly connecting wearable sensors to networks to remotely monitor patient health. *See* Ex. 1005 ¶ 3; Ex. 1009 ¶ 4; Ex. 1020, 3; Ex. 1021, 2–4; Ex. 1022, 1; Ex. 1024, 462, Ex. 1027, 9, 10, 15, 33, 35, 40–49; Ex. 1029, 221; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it. . . . If a person of ordinary skill can implement a predictable variation, § 103 likely

bars its patentability."). Patent Owner does not dispute this. *See* PO Resp. 14–32.

Petitioner also articulates sufficient reasoning with rational underpinning to demonstrate why a person of ordinary skill in the art would have modified Lisogurski's light source to incorporate the teachings of Carlson. *See* Pet. 24–26, 37–39 (citing/quoting Ex. 1003 ¶¶ 81–85, 117–122; Ex. 1009 ¶¶ 2, 4, 10, 48, 52, 67–69; Ex. 1011, 1:4–6, 1:16–18, 1:67–2:3, 3:50–53, 4:15–20, 4:63–67, 5:55–61, 9:46–60, 17:51–58, 37:6–18).

Lisogurski and Carlson teach complementary and combinable methods for increasing signal-to-noise in a wearable pulsoximeter in the presence of ambient light or sunlight. For example, Lisogurski "may alter the cardiac cycle modulation technique based on the level of noise, ambient light, [or] other suitable reasons." Ex. 1011, 9:46–48. In particular, Lisogurski "may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio. In some embodiments, the system may increase brightness throughout the cardiac cycle . . . ." *Id.* at 9:50–54 Carlson includes "electronic means for increasing the Signal-to-Noise . . . in rough (optical) environmental conditions, e.g., at changing light influences, such as sunlight, shadow, artificial light, etc." Ex. 1009 ¶ 10. In particular, Carlson pulses LEDs at a "frequency [that] is chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light. . . . [thereby] increasing significantly the Signal-to-Noise." *Id.* ¶ 69.

Thus, we agree with Petitioner that a person skilled in the art would have combined the teachings of Lisogurski and Carlson because the references teach "complementary designs and techniques in analogous systems," including "techniques for achieving the same objectives" of

increasing signal-to-noise in the presence of environmental noise such as ambient light or sunlight. Pet 25 (citing Ex. 1003 ¶¶ 81–84). Patent Owner does not dispute this. *See* PO Resp. 14–32.

2. Claims 5 and 13

a. A measurement system and wearable measurement device

Claim 13 recites a measurement system, and requires the system to include a wearable measurement device for measuring one or more physiological parameters. Ex. 1001 30:46–48. Petitioner demonstrates that Lisogurski's system 100/310, including sensor 102/312 for measuring blood oxygen saturation, meets this limitation. *See* Pet. 28 (citing Ex. 1011, 4:6–20, 17:55–59). Sensor 102/312 is a pulse oximeter that can be battery powered, wirelessly connected to monitor 104/314, and mounted on a user's fingertip, toe, earlobe, wrist, or thigh. Ex. 1011, 4:6–8, 4:15–20, 17:55–59. Patent Owner does not dispute this. *See* PO Resp. 13–42.

b. A light source including a plurality of LEDs

Claim 13 further requires the wearable measurement device to include a light source that includes a plurality of semiconductor sources that are light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, including a near-infrared wavelength between 700 and 2500 nanometers. Ex. 1001 30:48–55. Petitioner demonstrates how Lisogurski's sensor 102/312 meets this limitation. *See* Pet. 29–30 (citing Ex. 1011, 4:42–45, 7:38–8:3, 10:48–52, 10:56–63, 17:37–45, 19:25–31, Figs. 1, 3; Ex. 1003 ¶¶ 92–94). Sensor 102/312 can contain multiple LEDs that emit and direct light toward a subject's tissue, including an LED that emits red light, and an LED that emits infrared light having a wavelength

between 800 and 1000 nm. Ex. 1011, 10:48–52, 10:56–63. Patent Owner does not dispute this. *See* PO Resp. 13–42.

c. The light source configured to increase signal-to-noise by increasing a light intensity

Claim 13 further requires the light source to be configured to increase signal-to-noise by increasing a light intensity of at least one of the plurality of semiconductor sources. Ex. 1001 30:56–58. Petitioner demonstrates how Lisogurski's LED-based light source 130/316 meets this limitation. *See* Pet. 30–31 (citing Ex. 1011, 1:19–21, 1:44–46, 1:67–2:3, 5:55–6:6, 9:46–52, 9:57–60, 10:48–49, 11:38–41, 11:50–54, 14:49–55, 35:5–9; Ex. 1003 ¶¶ 95–98). Lisogurski teaches "the intensity of light source 130 and the timing of when light source 130 is turned on and off" is controlled by a light drive signal that "increase[s] the brightness of the light sources in response to . . . noise to improve the signal-to-noise ratio." Ex. 1011, 9:50–52, 11:50–54. Patent Owner does not dispute this. *See* PO Resp. 13–42.

d. The light source configured to increase signal-to-noise by increasing a pulse rate

Claim 13 further requires the light source to be configured to increase signal-to-noise by increasing a pulse rate of at least one of the plurality of semiconductor sources. Ex. 1001 30:58–60 ("the pulse rate limitation"). Petitioner contends Lisogurski alone teaches this limitation, and further contends the combination of Lisogurski and Carlson teaches this limitation. *See* Pet. 35–39. Patent Owner disputes this. *See* PO Resp. 14–32. We address Petitioner's contentions below, and notwithstanding Patent Owner's arguments to the contrary, find Petitioner demonstrates how Lisogurski alone, or in combination with Carlson, teaches or suggests the pulse rate limitation.

(1) Lisogurski alone

Petitioner argues that Lisogurski alone teaches the pulse rate limitation by teaching (1) the LED firing rate and brightness can be varied by the light drive signal, (2) the detector sampling rate is correlated to the LED firing rate and can be varied in the same way as the LED brightness, and (3) the LED brightness can be increased to increase signal-to-noise. *See* Pet. 35–36 (citing Ex. 1011, 2:1–2, 8:29–35, 9:46–52, 11:43–46, 11:52–55, 25:49–55, 33:47–49, 33:56–58, 35:7–9; 35:27–31, 37:6–22; Ex. 1003 ¶¶ 112–116). That is, Petitioner argues that Lisogurski teaches the pulse rate limitation because the LED firing rate and detector sampling rate are correlated and "increasing the sampling rate 'may result in more accurate and reliable physiological information.'" *Id.* at 36 (quoting Ex. 1011, 33:56–58; citing Ex. 1003 ¶ 116).

In our Institution Decision, we made a preliminary finding that Petitioner had not sufficiently demonstrated how Lisogurski teaches the pulse rate limitation because Lisogurski varies the LED brightness, LED pulse rate, and detector sampling rate to be synchronous with a cardiac cycle rather than to improve signal-to-noise. Dec. Inst. 30–31. For example, Lisogurski teaches:

> [T]he system may generate *a light drive signal that varies with a period the same as or closely related to the period of the cardiac cycle, thus generating a cardiac cycle modulation.* The system may vary parameters related to the light drive signal including drive current or light brightness, duty cycle, firing rate, modulation parameters, other suitable parameters, or any combination thereof.

Ex. 1011, 25:49–55 (emphases added). Lisogurski further teaches:

> It will also be understood that sampling rate is one of the components that may be *modulated in cardiac cycle modulation* as described above. It will also be understood that the earlier described embodiments relating to varying light output may also apply to sampling rate.

Id. at 35:5–9 (emphasis added).

Patent Owner at first agrees with this preliminary finding. *See* PO Resp. 16 ("In its Institution Decision, the Board correctly found that Lisogurski fails to disclose increasing SNR by increasing a pulse rate as claimed."). However, Patent Owner then makes the following statement:

> *Lisogurski teaches three different techniques for improving SNR*: (i) by increasing the "brightness" of the light source, (ii) by operating in a "high power mode without cardiac cycle modulation," and (iii) by *modulating the light signal to correlate with "physiological pulses" such as a "cardiac pulse," e.g.*, "diastole period cardiac modulation" or "systole period cardiac cycle modulation."

Id. at 15 (citing Ex. 1011, 25:66–26:14; 42:45–58) (emphases added) (internal citations omitted). In other words, Patent Owner expressly recognizes that Lisogurski improves signal-to-noise by modulating the light signal to correlate with, for example, a cardiac pulse. *Id.*

Petitioner replies that "when a person's heart rate increases" Lisogurski "increase[s] the sampling rate and emitter firing rate to become or remain synchronous with [the] cardiac cycle." Pet. Reply 10 (citing Ex. 1011, 25:49–55; 31:11–24; 31:39–55). Petitioner argues this allows Lisogurski to obtain "more accurate and reliable physiological information," which a person skilled in the art would have understood occurs "because [the] SNR is higher." *Id.* at 11 (quoting Ex. 1001, 33:46–52; citing Ex. 1003 ¶ 116). Petitioner further argues Patent Owner has admitted this because

"Omni admitted that cardiac cycle modulation is a technique for increasing SNR." *Id.* (quoting PO Resp. 15).

We are persuaded by Petitioner's argument, which is supported not only by intrinsic evidence and argument advanced by Patent Owner, but also testimony provided by Patent Owner's own witness. Lisogurski teaches correlating LED pulse rate and cardiac cycle rate, for example, by increasing LED pulse rate to match an increased cardiac cycle rate. *See* Ex. 1011, 25:46-55. Patent Owner acknowledges that Lisogurski teaches signal-to-noise can be improved by correlating the LED drive signal with a cardiac cycle signal. *See* PO Resp. 15 (citing Ex. 1011, 25:66–26:14, 42:45–58). For example, Lisogurski teaches that noise contributes "variations of 2.6%, 1.9%, and 3.8% to the computed pulse amplitudes of PPG[5] signal 2602, systole period modulated PPG signal 2604, and diastole period modulated PPG signal 2606." Ex. 1011, 42:50–54. Thus, increasing the LED firing rate to become synchronous with the systole period of an increased cardiac cycle rate can result in a physiological measurement having less noise (1.9%), and, therefore, an increased signal-to-noise ratio. Lisogurski also teaches that modulating an LED drive signal to match "particular segments of a respiratory cycle *may* provide an increased signal-to-noise ratio." Ex. 1011, 25:66–26:14 (emphasis added). Dr. MacFarlane, Patent Owner's expert, similarly testified that "increasing the [LED pulse] frequency *can*

[5] Lisogurski identifies a PPG or photoplethysmograph signal as "[a] signal representing light intensity versus time or a mathematical manipulation of this signal." Ex. 1001, 4:26–31. For example, a PPG signal can be a light absorption signal where "the amount of light absorbed may then be used to calculate any of a number of physiological parameters." *Id.* at 4:31–38.

sometimes increase the signal-to-noise ratio." Ex. 1060, 82:5–15 (emphasis added).

An LED is "configured" to increase signal-to-noise by increasing LED pulse rate when it is "capable" of doing so, even if it only does so some of the time. *See Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003) ("a prior art product that sometimes, but not always, embodies a claimed method nonetheless teaches that aspect of the invention"). This is so because whether signal-to-noise increases with increasing LED pulse rate depends on an external factor—the noise spectrum in the environment within which the device operates. But the claim is directed to the device itself, regardless of the environment within which it operates. Thus, a light source is "configured" to increase signal-to-noise by increasing LED pulse rate when it is "capable" of doing so, i.e., when the increased pulse rate allows the device to operate in a frequency range having less environmental noise. This is true, even if the device does not always do so. *See ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018) ("[A] prior art reference may anticipate or render obvious an apparatus claim . . . if the reference discloses an apparatus that is reasonably capable of operating so as to meet the claim limitations, even if it does not meet the claim limitations in all modes of operation.").

Accordingly, for the reasons discussed above, Petitioner has demonstrated how Lisogurski alone teaches the pulse rate limitation.

(2) Lisogurski and Carlson

Petitioner also argues that, to the extent Lisogurski alone does not teach the pulse rate limitation, the combination of Lisogurski and Carlson does. *See* Pet. 37–39. Specifically, Petitioner argues that because

Lisogurski "clearly identifies the importance of increasing signal-to-noise ratio" a person skilled in the art "would have been motivated to consider prior art teaching additional ways of improving signal-to-noise ratio." *Id.* at 37 (citing Ex. 1011, 9:50–52; Ex. 1003 ¶¶ 83–85, 120–121). Petitioner argues Carlson does so by pulsing an oximeter's LEDs at a frequency "outside the frequency spectrum of sunlight and of ambient light" in order to "reduce[] the effects of ambient light including sunlight." *Id.* at 37–38 (citing Ex. 1009 ¶¶ 67–69; Ex. 1003 ¶¶ 118–119).

Petitioner argues it would have been obvious to modify Lisogurski based on the teachings of Carlson because both references recognize the problem of ambient light noise "and the need to offset its negative impact on the signal-to-noise ratio." *Id.* at 38 (citing Ex. 1009 ¶¶ 67–69; Ex. 1011 9:46–60; Ex. 1003 ¶¶ 118–121). Petitioner argues Lisogurski teaches adjusting the LED firing rate "in response to changes in environmental conditions, such as changes in background noise or ambient light." *Id.* (citing Ex. 1011, 1:67–2:3, 5:55–61, 9:46–60, 37:6–18; Ex. 1003 ¶¶ 120–122). Petitioner further argues Carlson teaches "increasing the modulation frequency of the pulsed LEDs improves the signal-to-noise ratio" by teaching the LED "pulse frequency ('*pulse rate*') is 'chosen in such a way that it is outside the frequency spectrum of sunlight and ambient light' and it could be '1000 Hz' or 'can be chosen at any other frequency, as e.g. 2000 Hz or even higher.'" *Id.* at 37–39 (quoting Ex. 1009 ¶ 69; citing Ex. 1003 ¶¶ 119–121). Thus, Petitioner argues, "a skilled person would have found it obvious to configure Lisogurski to increase the firing rate (frequency) of LEDs as taught by Carlson, given that Carlson teaches that increasing the

modulation frequency of the pulsed LEDs improves the signal-to-noise." *Id.* at 39 (citing Ex. 1003 ¶ 120–121).

In our Institution Decision, we made a preliminary finding that Petitioner was reasonably likely to show how the combination of Lisogurski and Carlson teaches the pulse rate limitation because:

> Together, the references teach that a pulsoximeter can detect a change in background noise and modify the LED firing rate based on the detected change (as taught by Lisogurski), and can modify the frequency of the LED firing rate to be greater than the frequency of the background noise (as taught by Carlson).

Dec. Inst. 36 (citing Ex. 1011, 1:67–2:3, 37:6–9; Ex. 1009 ¶¶ 65, 69). Patent Owner argues this is "an obviousness argument the Petition did not assert." PO Resp. 31. Petitioner disagrees, arguing "the Board did not advance a new argument in its Institution Decision." Pet. Reply 24–25.

We agree with Petitioner. The *Petition* states: Lisogurski "adjust[s] various parameters of light emitted by the LEDs to ensure an adequate signal-to-noise ratio," including "drive current or light brightness, duty cycle, [and] ***firing rate***." Pet. 35 (citing Ex. 1011, 25:49–55, 27:44–52, 37:6–22) (internal citations omitted). We agree. For example, Lisogurski measures a physiological parameter in cardiac cycle modulation mode using "a light drive signal that varies with a period the same as . . . the period of the cardiac cycle," i.e., a 1 second period corresponding to a firing rate of 1 Hz. Ex. 1011, 5:48–54, 25:46–52. Lisogurski "detect[s] a change in background noise [or] . . . ambient light" and "perform[s] a physiological measurement in a second mode." *Id.* at 37:6–9, 37:14–15. The second mode, for example, can (a) "stop cardiac cycle modulation," (b) "increase emitter intensity" during cardiac cycle modulation, (c) "lengthen the 'on'

periods" (i.e., duty cycle) of cardiac cycle modulation, or (d) "alter the cardiac cycle modulation" by changing the LED firing rate as shown in Figure 8B. *Id.* at 37:15–22. That is, the second mode can differ from cardiac cycle modulation by changing any of the light drive signal parameters, i.e., the "drive current or light brightness, duty cycle, firing rate . . . or any combination thereof." *Id.* at 27:44–49. Thus, *in the Petition*, Petitioner cites sufficient evidence to persuasively demonstrate how Lisogurski teaches (1) modulating an LED by pulsing it at a 1 Hz rate that matches a cardiac cycle, (2) detecting ambient light noise, and (3) changing the LED modulation to operate in a second mode by changing one or more of the LED brightness, duty cycle (on time per cycle), or firing rate.

The *Petition* also states: Carlson teaches "pulsing the LEDs reduces the effects of ambient light including sunlight" when "the pulse frequency ('*pulse rate*') is 'chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light." Pet. 37–38 (quoting Ex. 1009 ¶ 69). We agree. For example, Carlson teaches various means to improve a pulsoximeter's signal-to-noise. Ex. 1009 ¶¶ 62–69. These include "us[ing] a light source modulation to temporarily modulate the optical radiation of the LED" at a frequency that "is chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light . . . in the range of above approximately 1000 Hz." *Id.* ¶¶ 64, 69.

Finally, the *Petition* also states: Lisogurski "can readily be modified to incorporate the Carlson technique, given that Lisogurski teaches that the firing rate of the LEDs can be adjusted in response to changes in environmental conditions, such as changes in background noise or ambient light." Pet. 38. We agree. As discussed above, Lisogurski teaches (1)

taking a physiological measurement in cardiac cycle modulation mode using LEDs modulated at a 1Hz pulse rate, (2) exiting the cardiac cycle modulation mode upon detecting ambient light noise, and (3) taking the measurement in a second mode that varies any combination of LED brightness, duty cycle, or firing rate, and Carlson teaches (4) taking a physiological measurement using an LED modulated at a 1000 Hz pulse rate to reduce ambient light noise. *See* Pet. 35, 37 (citing Ex. 1011, 25:49–55, 27:44–52, 37:6–22; Ex. 1009 ¶ 69) (internal citations omitted). Thus, Petitioner cites sufficient evidence *in the Petition* to demonstrate how the combination of Lisogurski and Carlson teaches the pulse rate limitation.

Patent Owner next argues that the combination of Lisogurski and Carlson does not teach the pulse rate limitation because "neither reference teaches nor suggests a ***device*** 'configured to' ***increase*** a pulse rate to increase SNR" PO Resp. 28. That is, Patent Owner argues the combination fails to teach the pulse rate limitation because both Lisogurski[6] and Carlson[7]

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[6] As discussed in § II.F.2.d(1), *supra*, we find Lisogurski teaches the pulse rate limitation, e.g., by increasing the LED pulse rate to match an increased cardiac cycle rate.

[7] Patent Owner argues Carlson fails to teach the pulse rate limitation because Carlson discloses temporarily modulating a continuous light source to operate "at a chosen single, fixed pulse rate" that is not increased. PO Resp. 17. The concurrence disagrees. We need not resolve that issue here, however, because we find Lisogurski teaches switching the LED pulse rate from a cardiac cycle mode (1 Hz pulse rate) to a second mode that reduces ambient light noise, and Carlson teaches pulsing the LED at 1000 Hz to reduce ambient light noise. That is, the combination teaches increasing signal-to-noise by increasing the LED pulse rate from 1 Hz to 1000 Hz.

fail to teach it. *Id.* at 25–26.

We are not persuaded by this argument because it fails to consider the combined teachings of Carlson and Lisogurski. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Rather, the test for obviousness is "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller 642 F.2d 413, 425* (Fed. Cir. 1981). As discussed above, the combined teachings of Lisogurski and Carlson are to (1) pulse an LED at 1 Hz in a cardiac cycle modulation mode, (2) detect ambient light noise, and (3) switch to a second mode to reduce the ambient light noise, such as a mode that pulses the LED at 1000 Hz. Thus, the proposed combination of Lisogurski and Carlson is the simple "substitution of one element for another known in the field" to achieve a predictable result. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Accordingly, for the reasons discussed above, we find Petitioner has demonstrated that the combination of Lisogurski and Carlson teaches a light source configured to increase signal-to-noise by increasing LED pulse rate.

e. A plurality of lenses

Claim 13 further requires the wearable measurement device to include a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample. Ex. 1001 30:60–63. Petitioner demonstrates how Lisogurski's wireless sensor 102/312, when combined with the knowledge of a person of ordinary skill in the art or the teachings of Carlson, meets this limitation. See Pet. 39–43.

First, Petitioner demonstrates how a person skilled in the art would have known that LEDs are often covered by lensing encapsulants, and would have selected such LEDs for wireless sensor 102/312 in order to "direct more of the light produced by the LED outward toward the tissue," thereby improving the efficiency of wireless, battery-powered, sensor 102/312. *Id.* at 39–40 (citing Ex. 1003 ¶¶ 124–128; Ex. 1035, 97–98, 191–199). Second, Petitioner demonstrates that a person skilled in the art, knowing "a lens is a 'basic building block' of an optical sensor," would have included lenses in Lisogurski's wireless sensor 102/312. *Id.* at 41 (citing Ex. 1003 ¶ 129; Ex. 1019, 765). Third, Petitioner demonstrates that a person skilled in the art would have included lenses in Lisogurski's wireless sensor 102/312 because Carlson teaches the advantages of doing so. *Id.* at 41–43 (citing Ex. 1009 ¶¶ 13, 14, 24, 62, Fig. 4; Ex. 1003 ¶¶ 130–133). Figure 4 of Carlson is reproduced below.

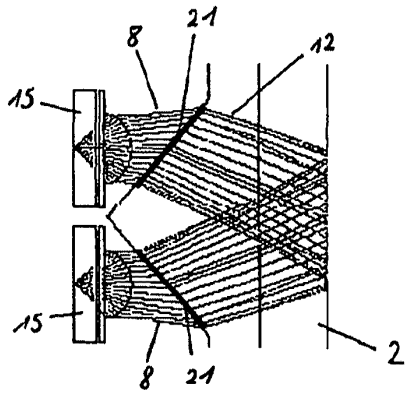


Figure 4

Figure 4 of Carlson schematically illustrates "two light emitting sources for an oximetric sensor, including beam shaping optics." Ex. 1009 ¶ 35. The beam shaping optics include "two lenses 21 that receive light beams 8

emitted by LEDs 15 . . . and deliver light bundles or beams 12 to sample 2." Pet. 42 (citing Ex. 1009 ¶¶ 54, 62). Carlson teaches lenses 21 "increase the optical signal power without increasing the actual power used by the system," thereby "increasing the Signal/Noise . . . ratio." *Id.* at 43 (citing Ex. 1009 ¶¶ 10, 14). Lisogurski teaches the importance of both reducing power consumption and increasing signal-to-noise ratio. *Id.* (citing Ex. 1003 ¶¶ 84, 118, 133–134; Ex. 1011, 14:40–55, 37:6–20). Therefore, a person skilled in the art would have incorporated Carlson's lenses 21 into Lisogurski's wireless sensor 102/312 to increase its optical signal power and signal-to-noise ratio without increasing its actual power. Patent Owner does not dispute this. See PO Resp. 14–32.

f. A receiver

Claim 13 further requires the wearable measurement device to include a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, and further configured to be synchronized to pulses of the light source. Ex. 1001, 30:64–31:3. Petitioner identifies Lisogurski's detector 140/318 and front end processing circuitry 150 in monitor 104 as the receiver. *See* Pet. 45 ("The detector described in Lisogurski is connected to front end processing circuitry (together a '*receiver configured to receive and process*')"). Petitioner provides a modified version of Figure 1 of Lisogurski, reproduced below, to illustrate the components of such a receiver.

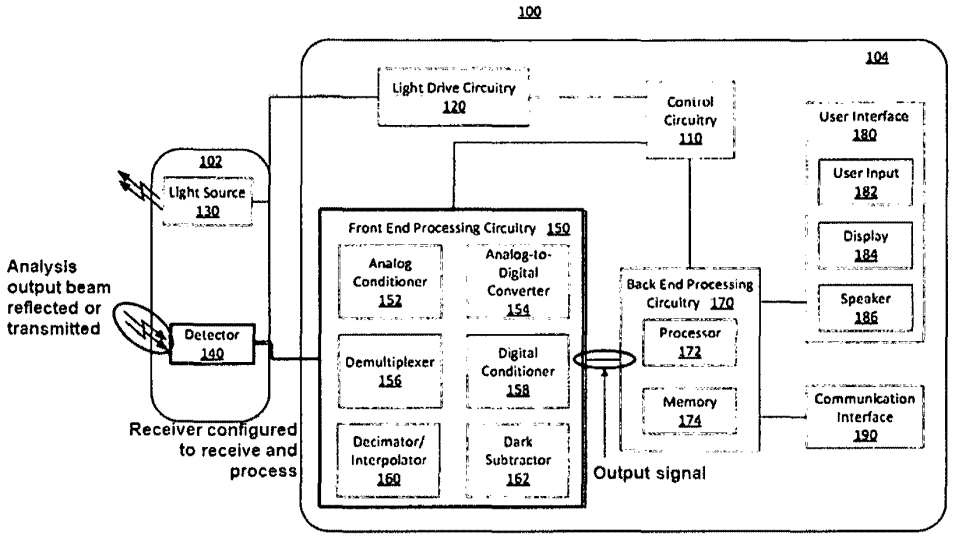


FIG. 1

The Figure is a Petitioner-modified version of Figure 1 of Lisogurski showing Petitioner's proposed modification of sensor 102 to include front end processing circuitry 150 from monitor 104. For the reasons discussed in § II.F.1, *supra*, Petitioner demonstrates why a person skilled in the art would have modified Lisogurski's wireless sensor 102/312 to include front end processing circuitry 150. These include Lisogurski's express suggestion, the industry trend to make wireless sensors for remote healthcare and personal fitness tracking, and the need to convert "the analog signal output from the detector . . . to digital form for wireless transmission. . . . in the sensor where the signal is captured." *Id.* at 48–49 (quoting Ex. 1011, 16:2–9; citing Ex. 1003 ¶¶ 144–146). Patent Owner does not dispute this. *See* PO Resp. 8–32.

Petitioner demonstrates how Lisogurski's receiver (i.e., detector 140/318 and front end processing circuitry 150) meets the "receiver" limitations. See Pet. 44–45 (citing/quoting Ex. 1011, 11:9–10, 11:14–17,

11:20–27, 11:41–46, 12:42–45, 17:40–42, Figs. 1, 3; Ex. 1003 ¶ 139). The receiver receives and processes the output beam because it includes detector 140/318, which "detect[s] the light that is reflected by or has traveled through the subject's tissue" and "convert[s] the intensity of the received light into an electrical signal." Ex. 1011, 11:14–17, 17:39–42, Figs. 1, 3. The receiver generates an output signal because front end processing circuitry 150 "receive[s] a detection signal from detector 140 and provide[s] one or more processed signals to back end processing circuitry 170." *Id.* at 11:20–27, 12:42–45. The receiver is synchronized to the light source's pulses of light because the "front end processing circuitry may use the timing control signals to operate synchronously with light drive circuitry 120," i.e., the circuitry that drives Lisogurski's LED-based light source. *Id.* at 11:41–46, 11:50–54. Patent Owner does not dispute this. *See* PO Resp. 14–32.

g. A personal device

Claim 13 further requires a personal device that includes a wireless receiver and transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen. Ex. 1001 31:3–7. Petitioner identifies Lisogurski's monitor 104/314, modified as described above to include only backend processing circuitry 170, user interface 180, and communication interface 190, as the personal device. *See* Pet. 49–53. Petitioner provides a modified version of Figure 1 of Lisogurski, reproduced below, to illustrate the components of such a personal device.

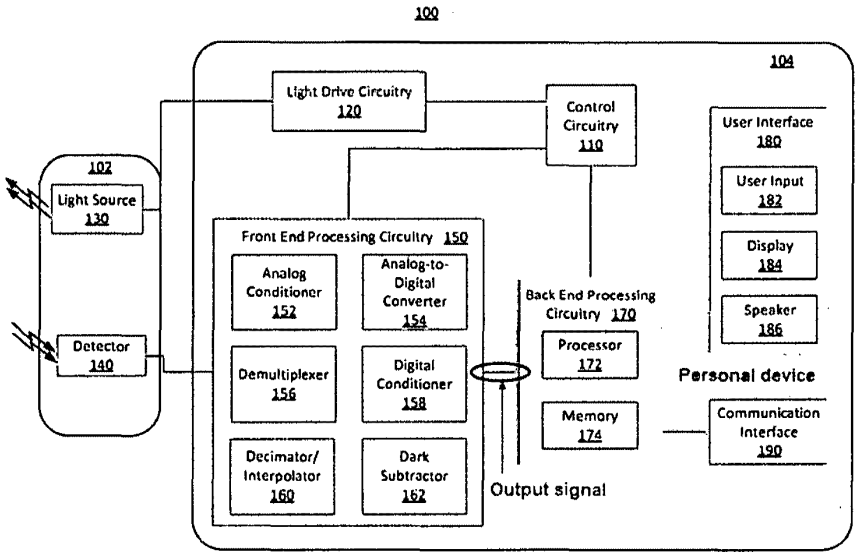


FIG. 1

The Figure is a Petitioner-modified version of Figure 1 of Lisogurski showing Petitioner's proposed modification of monitor 104 to include only backend processing circuitry 170, user interface 180, and communication interface 190. Petitioner demonstrates why a person skilled in the art would have modified Lisogurski's monitor 104 in the manner proposed, including Lisogurski's express suggestion and the industry trend to make wireless sensors for personal fitness tracking that transmit monitored physiological parameters to a personal device. See § II.F.1, *supra*.

Petitioner demonstrates how backend processing circuitry 170 includes microprocessor 172, user interface 180 includes a display, a microphone, a speaker, buttons, and a touch screen, and communication interface 190 includes wireless receivers and transmitters for wireless communications. *Id.* at 51 (citing Ex. 1011, 15:19–23, 15:49–56, Fig. 1). Patent Owner does not dispute this. *See* PO Resp. 14–32.

Claim 13 further requires the personal device to be configured to receive and process at least a portion of the output signal, to store and display the processed output signal, and to transmit at least a portion of the processed output signal over a wireless transmission link. Ex. 1001 31:7–12. Petitioner demonstrates how Lisogurski's monitor 104/314 (i.e., backend processing circuitry 170, user interface 180, and communication interface 190) meets these personal device limitations. See Pet. 50–53 (citing/quoting Ex. 1011, 14:60–15:16, 15:30–35, 15:43-48, 15:55-57, 18:11-15, 18:49-65, 26:55-60, 27:31–36, Fig. 1; Ex.1003, ¶¶150–153).

Monitor 104/314 receives and processes the output signal from the receiver (i.e., detector 140/318 and front end processing circuitry 150) because processor 172 in back end processing circuitry 170 "receive[s] and process[es] physiological signals [i.e., the output signal] received from front end processing circuitry 150" and "determine[s] one or more physiological parameters based on the received physiological signals." Ex. 1011, 14:56–64, Fig. 1. Monitor 104/314 displays the processed output signal (i.e., a determined physiological parameter) because it includes display 184/320, which can "display, for example, an estimate of a subject's blood oxygen saturation generated by monitor 104." *Id.* at 15:30–35, Figs. 1, 3. Monitor 104/314 stores the processed output signal because it includes memory 174, which can store "historical information [measured in] previous cardiac cycles." *Id.* at 14:64–15:16, 27:31–36, Fig. 1. Finally, monitor 104/314 transmits the processed output signal over a wireless link because communications interface 190 can use a wireless communications protocol to transmit the signal to MPPM 326 for display on remote display 328. *Id.*

at 15:43–57, 18:11–15, 18:49–65, 26:55–60, Figs. 1, 3. Patent Owner does not dispute this. *See* PO Resp. 14–32.

h. A remote device

Claim 13 further requires a remote device configured to receive over the wireless transmission link an output status including at least a portion of the processed output signal, to process the received output status to generate and store processed data, and to store a history of at least a portion of the received output status over a specified period of time. Ex. 1001, 31:13–20.

Petitioner demonstrates how Lisogurski's MPPM 326 meets these limitations. *See* Pet. 53–55 (citing Ex. 1011, 15:43–48, 18:49–53, 18:58–62, 20:8–13, 26:51–60; Ex. 1003 ¶¶ 154–163). MPPM 326 can be wirelessly coupled to monitor 104/314 and receive an output status that includes the processed output signal (i.e., a physiological parameter) over a wireless link. Ex. 1011, 15:43–48, 18:49–56, 18:58–62, Fig. 3. MPPM 326 can process the received output status to generate and store processed data, e.g., because monitor 104/314 can "publish" the data. *Id.* at 26:51–60. According to the unrebutted testimony of Dr. Anthony, MPPM 326 "would need to process the data and then store it" in order to "publish" it. Ex. 1003 ¶ 155. MPPM 326 can also store a history of the output status over a period of time because it can perform statistical analysis on a history of physiological parameter measurements, e.g., to determine the average value and standard deviation of the physiological parameter measurements. Ex. 1011, 20:8–13. Patent Owner does not dispute this. *See* PO Resp. 14–32.

For the reasons discussed above, we find Petitioner has demonstrated by a preponderance of evidence that the combination of Lisogurski and Carlson teaches all the limitations of claim 13 and that claim 13 is

unpatentable over the combination. As discussed in § II.B, *supra*, claim 5 is broader than, but substantially similar in scope to, claim 13. Petitioner's analysis of claim 5, therefore, relies on its analysis of claim 13. *See* Pet. 55–57. Accordingly, we find Petitioner has demonstrated by a preponderance of evidence that claim 5 is unpatentable over the combination of Lisogurski and Carlson for the same reasons discussed above for claim 13.

3. Claims 7 and 15

Claim 15 depends from claim 13, and further requires the remote device to be configured to transmit at least a portion of the processed data to one or more other locations selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and to be capable of transmitting information related to a time and a position associated with the at least a portion of the processed data. Ex. 1001, 32:1–9. Claim 7 depends from claim 5, and adds the same limitation to claim 5. *Compare id.* at 30:15–23, *with id.* at 32:1–9.

Petitioner demonstrates how the combination of Lisogurski and Carlson teaches these limitations. *See* Pet. 58–59 (citing Ex. 1011, 15:43–57, 18:11–15, 18:48–67, 20:53–60; Ex. 1009 ¶ 78; Ex. 1003 ¶¶ 176–178). As discussed in § II.F.2, *supra*, Lisogurski's MPPM 326 is a remote device that is wirelessly coupled to and receives an output signal from monitor 104/314 (i.e., a personal device) and that can be "coupled to a network to enable the sharing of information with servers or other workstations," (i.e., a cloud-based server). Ex. 1011, 15:43–48, 18:49–65, Fig. 3. Carlson teaches the server can be in a hospital's network or a doctor's network. Ex. 1009 ¶ 78. Carlson further teaches a wearable sensor, such as Lisogurski's

wearable sensor 102/312, can include a GPS receiver to enable it to communicate a patient's location to a monitoring hospital or doctor when the patient's physiological data in not within a predetermined range. *Id.*

Petitioner also provides sufficient reasoning, with a rational underpinning, to combine the teachings of Lisogurski and Carlson in the proposed manner. Specifically, Petitioner argues that a person skilled in the art would have found it obvious "to modify Lisogurski in the manner suggested by Carlson in order to use GPS data to track the location of a person wearing a sensor" to be able to "identify where the person was in case of emergency to allow any medical personnel at the central location to find the person to provide assistance." Pet. 59 (citing Ex. 1003 ¶ 178). Patent Owner does not dispute this. *See* PO Resp. 14–32.

For the reasons discussed above, we find Petitioner has demonstrated by a preponderance of evidence that claims 7 and 15 are unpatentable over the combination of Lisogurski and Carlson.

4. Claims 8 and 16

Claim 16 depends from claim 13, and further requires the receiver to be located a first distance from and to receive a first signal from a first one of the plurality of light emitting diodes, and to be located a different, second distance from and to receive a second signal from a second one of the plurality of light emitting diodes. Ex. 1001, 32:10–15. Claim 8 depends from claim 5, and adds the same limitations to claim 5. *Compare id.* at 30:24–30, *with id.* at 32:10–15.

Petitioner demonstrates how Lisogurski teaches these limitations. *See* Pet. 60–62 (citing Ex. 1011, 7:38–8:3, 12:29–33, 17:39–45, Figs. 2A, 2B; Ex. 1009 ¶ 78; Ex. 1003 ¶¶ 181–183). Lisogurski teaches "[s]ensor unit 312

may include one or more light source[s] 316 for emitting light at one or more wavelengths" and "[o]ne or more detector[s] 318." Ex. 1011, 17:37–42. Light sources 316 and detectors 318 may be arranged in "[a]ny suitable configuration," and "may be spaced apart." *Id.* at 17:42–45. Light sources 316 can include "a high efficiency infrared (IR) LED" and one or more "lower efficiency red LEDs." *Id.* at 7:58–61. The red and IR LEDs can be flashed on and off, during separate "Red light LED 'on' period[s] 202" and "IR light 'on' period[s] 204." *Id.* at 12:23–33, Figs. 2A, 2B. During these periods, detector 318 "detect[s] the light that is reflected by or has traveled through the subject's tissue," i.e., detector 318 detects a first signal from a first LED (red light from red LED) and a second signal from a second LED (IR light from IR LED). *Id.* at 12:29–33, 17:39–42, Figs. 2A, 2B.

Petitioner argues, and we agree, that because "[t]here are just two options for how two LEDs can be spaced in relation to a detector: either they are each the same distance from the detector or they are different distances from it," a person of ordinary skill in the art reading Lisogurski's disclosure that the sensors can be spaced apart would have "immediately envisioned both options." Pet. 61 (citing Ex. 1003 ¶ 181, *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)). Petitioner further argues, and we agree, that because "[t]here are just two choices for how to space the LEDs from the detector . . . the selection of one of those two ways is a simple design choice." *Id.*, n.8. Patent Owner does not dispute this. *See* PO Resp. 14–32.

For the reasons discussed above, we find Petitioner has demonstrated by a preponderance of evidence that claims 8 and 16 are unpatentable over the combination of Lisogurski and Carlson.

5. Claims 9 and 17

Claim 17 depends from claim 16, and further requires the receiver's output signal to be generated in part by comparing the first and second signals. Ex. 1001, 32:16–17. Claim 9 depends from claim 8, and adds the same limitations to claim 8. *Compare id.* at 30:31–32, *with id.* at 32:16–17.

Petitioner demonstrates how Lisogurski teaches this limitation. *See* Pet. 63 (citing Ex. 1011, 4:45–56; Ex. 1019, 769–770; Ex. 1003 ¶ 183). As discussed in § II.F.4, *supra*, Lisogurski teaches separately detecting red light (first signal) and IR light (second signal) at different points in a timing cycle, and further teaches "comparing the intensities of two wavelengths at different points in the pulse cycle . . . to estimate the blood oxygen saturation of hemoglobin in arterial blood." Ex.1011, 4:45-51. Specifically, Lisogurski teaches "determin[ing] blood oxygen saturation using two wavelengths of light and a ratio-of-ratios calculation." *Id.* at 4:52–56.

For the reasons discussed above, we find Petitioner has demonstrated by a preponderance of evidence that claims 9 and 17 are unpatentable over the combination of Lisogurski and Carlson.

6. Claim 10

Claim 10 depends from claim 5, and further requires the output signal to include one or more physiological parameters, and the remote device to be capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time. Ex. 1001, 30:33–57. As discussed in § II.B, *supra*, independent claim 5 is broader than independent claim 13 because it does not require the measurement device to output one or more physiological parameters and does not require the remote device to be capable of storing a history of the one or more physiological

parameters over a specified period of time. *Compare id.* at 29:43–30:10, *with id.* at 30:46–31:20. Claim 10 adds these limitations to claim 5, giving claim 10 the same scope as claim 13. *Id.* at 30:33–37.

Petitioner relies on its analysis of claim 13 to teach the limitations of claim 10. *See* Pet. 63. For the reasons explained in § II.F.2, *supra*, Petitioner demonstrates by a preponderance of evidence that the combination of Lisogurski and Carlson teaches all of the limitations of claim 10, and that claim 10 is unpatentable over the combination of Lisogurski and Carlson.

G. Patentability of claims 8, 9, 16, and 17 over Lisogurski, Carlson, and Mannheimer

Petitioner argues claims 8, 9, 16, and 17 are unpatentable as obvious over the combination of Lisogurski, Carlson, and Mannheimer. *See* Pet. 63–69. For the reasons stated below, we find Petitioner has demonstrated by a preponderance of evidence the unpatentability of these claims over Lisogurski, Carlson, and Mannheimer.

1. Petitioner's proposed combination

Petitioner proposes combining Lisogurski's physiological monitoring system shown in Figures 1 and 3, in which sensor 102/312 wirelessly communicates with monitor 104/314, with Carlson's teachings regarding pulsing an LED at a frequency that increases signal-to-noise in a wireless pulse oximeter sensor as discussed in § II.F.1, *supra*. We agree that a person skilled in the art would have been motivated to combine these references for the reasons discussed there. Petitioner further proposes combining Lisogurski and Carlson with the teachings of Mannheimer to detect light at a receiver placed first and second distances from first and second LEDs. *See* Pet. 64–66 (citing/quoting Ex. 1003 ¶ 192–194; Ex. 1008, 3:25–35, 3:38–40,

5:1–5, 5:58–62, 6:17–36, 6:66–7:4. Figs. 1B, 2, 4; Ex. 1011, 17:45, 19:42–50, 44:43–48).

Petitioner articulates sufficient reasoning with rational underpinning to combine the teachings of Mannheimer with the teachings of Lisogurski and Carlson. Mannheimer, like Lisogurski and Carlson, is directed to a "pulse oximetery monitoring and measurement system" that "uses one or more LEDs to alternately emit red and infrared light." Pet. 64 (citing Ex. 1008, 6:17–36, 6:66–7:4. Figs. 2, 4). Lisogurski teaches "light is attenuated differently depending on the tissue" with which it interacts, including skin, and Mannheimer teaches a method for removing interference from skin "by using signals detected from LEDs spaced different distances from a detector." *Id.* at 65 (citing Ex. 1011, 19:42–50, 44:43–48; Ex. 1008, 3:25–35, 5:1–5; Ex. 1003 ¶ 193).

Lisogurski teaches using "multiple light sources and detectors, which may be spaced apart," but does not "identify the spacing that should be used" or the reason to space the detectors apart. *Id.* at 65–66 (citing Ex. 1011, 17:45, Ex. 1003 ¶ 194). Mannheimer, by contrast, teaches a specific configuration of light sources and detectors consisting of a single detector spaced distances r_1 and r_2 from red and IR LEDs, respectively, and using that configuration to measure light absorption attributable to subdermal layer 12, a tissue layer of interest, based on r_1 and r_2. Ex. 1008, 3:25–35, 3:38–40, 5:58–62, 6:17–36, Figs. 1B. Mannheimer teaches this configuration "differs from the conventional single detector pulse oximetry algorithm in that the skin layer signals are excluded from the measurement." *Id.* at 5:1–5. Thus, Petitioner demonstrates that a person skilled in the art would have incorporated Mannheimer's teachings into Lisogurski to allow Lisogurski to

measure light absorption from a specific layer of tissue by removing or excluding the light absorption due to surface tissue layers. Patent Owner does not dispute this. *See* PO Resp. 14–32.

2. Claims 8 and 16

Claim 16 depends from claim 13, and further requires the receiver to be located a first distance from and to receive a first signal from a first one of the plurality of light emitting diodes, and to be located a different, second distance from and to receive a second signal from a second one of the plurality of light emitting diodes. Ex. 1001, 32:10–15. Claim 8 depends from claim 5, and adds the same limitations to claim 5. *Compare id.* at 30:24–30, *with id.* at 32:10–15.

Petitioner demonstrates how Mannheimer teaches this limitation by disclosing detector 24 receiving first signal 18 from first LED 17 located first distance r_1 from detector 24, and receiving second signal 22 from second LED 16 located second distances r_2 from detector 24. Pet. 66–67 (citing Ex. 1008, 3:18–24, 5:58–62. Fig. 1B; Ex. 1003 ¶ 198). Patent Owner does not dispute this. *See* PO Resp. 14–32.

For the reasons discussed above, we find Petitioner has demonstrated by a preponderance of evidence that claims 8 and 16 are unpatentable over the combination of Lisogurski, Carlson, and Mannheimer.

3. Claims 9 and 17

Claim 17 depends from claim 16, and further requires the receiver's output signal to be generated in part by comparing the first and second signals. Ex. 1001, 32:16–17. Claim 9 depends from claim 8, and adds the same limitations to claim 8. *Compare id.* at 30:31–32, *with id.* at 32:16–17.

Petitioner demonstrates how Mannheimer teaches this limitation by

"calculating an arterial oxygen saturation level" related to "the arterial blood saturation of . . . deeper tissue" by calculating "a ratio R from I_1 and I_2," where I_1 is a first intensity "corresponding to the [first] signal 18 detected from light emitted by [first LED] E_1" and I_2 is a second intensity "corresponding to the [second] signal 2[2] detected from light emitted by [second LED] E_2." Pet. 68–69 (quoting/citing Ex. 1008, 2:16–18, 3:35–5:9, 5:23–57; Ex. 1003 ¶¶ 202–204). Patent Owner does not dispute this. *See* PO Resp. 14–32.

For the reasons discussed above, we find Petitioner has demonstrated by a preponderance of evidence that claims 9 and 17 are unpatentable over the combination of Lisogurski, Carlson, and Mannheimer.

III. CONCLUSION

We have reviewed the Petition, Patent Owner Response, Petitioner Reply, and Patent Owner Sur-Reply. We have considered all of the evidence and arguments presented by Petitioner and Patent Owner, and have weighed and assessed the entirety of the evidence as a whole.

We determine, on this record, that Petitioner has demonstrated by a preponderance of evidence that claims 5, 7–10, 13, and 15–17 of the '533 patent are unpatentable over Lisogurski and Carlson.[8] We further determine

[8] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to

that Petitioner has demonstrated by a preponderance of evidence that claims 8, 9, 16, and 17 of the '533 patent are unpatentable over Lisogurski, Carlson, and Mannheimer.

Claims	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
5, 7–10, 13, 15–17	103	Lisogurski, Carlson	5, 7–10, 13, 15–17	
8, 9, 16, 17	103	Lisogurski, Carlson, Mannheimer	8, 9, 16, 17	
Overall Outcome			5, 7–10, 13, 15–17	

IV. ORDER

It is hereby:

ORDERED that claims 5, 7–10, 13, and 15–17 of the '533 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Lisogurski and Carlson;

FURTHER ORDERED that claims 8, 9, 16, and 17 of the '533 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Lisogurski, Carlson, and Mannheimer; and

FURTHER ORDERED that this Decision is final, and a party to this proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Case IPR2019-00916
Patent 9,651,533 B2

HORVATH, Administrative Patent Judge, Concurring

I concur with the panel decision, and write separately to express additional reasons I find Lisogurski alone or in combination with Carlson teaches the pulse rate limitation.

A. Lisogurski alone

As noted in § II.F.2.d(1) of the panel decision, Petitioner contends that Lisogurski alone teaches the pulse rate limitation. *See* Pet. 35–36. Although Patent Owner disputes this contention, Patent Owner nevertheless states that Lisogurski teaches "three different techniques for improving SNR," including "by modulating the light signal to correlate with 'physiological pulses' such as a 'cardiac pulse.'" PO Resp. at 15. Petitioner argues this statement is an admission that Lisogurski teaches the pulse rate limitation,

e.g., by increasing the LED pulse rate to match an increased cardiac cycle rate. *See* Pet. Reply 11.

I agree. Patent Owner's statement characterizing Lisogurski is an admission by a party-opponent under the Federal Rules of Evidence, which apply to this proceeding. *See* 37 CFR § 42.62(a). Petitioner offers the statement "against an opposing party." Fed. R. Evid. 801(d)(2) (2014); *see also* Pet. Reply 11 ("Omni admitted that cardiac cycle modulation is a technique for increasing SNR."). The statement appeared in Patent Owner's principal brief and was made by Patent Owner's designated counsel, who was appointed by Patent Owner "to transact all business . . . associated with any *inter partes* review . . . before the Patent Trial & Appeal Board pertaining to the above-captioned ['533] patent." PO Resp. 15, 32; Paper 8, 1–2; Paper 9, 2. Thus, the statement was made by an "agent or employee on a matter within the scope of that relationship and while it existed." Fed. R. Evid. 801(d)(2)(D) (2014). This makes the statement an admission that Lisogurski's light source is configured to increase signal-to-noise by increasing the LED firing rate to match an increased cardiac cycle rate. *See Cook Group Inc. v. Boston Scientific Scimed, Inc.*, 809 F. App'x 990, 1000 (Fed. Cir. 2020) ("It is well established . . . that a statement made by a party in an individual or representative capacity may be offered as evidence against that party.").

Given the disclosures in Lisogurski identified by Patent Owner and discussed in the panel decision at § II.F.2.d(1), particularly Lisogurski's disclosure that modulating an LED drive signal to match "particular segments of a respiratory cycle may provide an increased signal-to-noise ratio," I find Patent Owner's admission that Lisogurski teaches "improving

SNR" by "modulating the light signal to correlate with 'physiological pulses' such as a 'cardiac pulse'" to be credible evidence that Lisogurski teaches increasing signal-to-noise by increasing the LED pulse rate to match an increased cardiac cycle rate. PO Resp. at 15; Ex. 1011, 25:66–26:14; *see also Nekolny v. Painter*, 653 F.2d 1164, 1172 (7th Cir. 1981), *cert. denied*, 455 U.S. 1021 (1982) (finding admissions are credible evidence because "an agent or servant who speaks on any matter within the scope of his agency or employment during the existence of that relationship, is unlikely to make statements damaging to his principal or employer unless those statements are true.").

B. Lisogurski and Carlson

As also noted in § II.F.2.d(1) of the panel decision, Petitioner also argues that the combination of Lisogurski and Carlson teaches the pulse rate limitation. *See* Pet. 37–39. In our Institution Decision, we made a preliminary finding that Petitioner was reasonably likely to show how the combination of Lisogurski and Carlson teaches the pulse rate limitation because Carlson teaches it. *See* Dec. Inst. 34–35. Specifically, we found:

> Carlson teaches that "standard pulsoximeter sensors suffer from signal instability and insufficient robustness versus environmental disturbances," and provides, as an example, disturbances caused when a person wearing a sensor experiences alternating cycles of sunshine and shade "at a certain frequency" while walking or driving along a tree-lined avenue. Ex. 1009 ¶¶ 4, 68. Carlson teaches removing such disturbances by pulsing the sensor LEDs at a frequency that is "outside the frequency spectrum of sunlight[9] and of ambient

[9] Carlson identifies the "frequency spectrum" of sunlight as 0 Hz. *See* Ex. 1009, Fig. 7b. We understand this passage of Carlson to be referring to

> light" in order to "increas[e] significantly the Signal-to-Noise." *Id.* ¶ 69. Carlson does not teach pulsing the LEDs at any particular frequency, but instead teaches pulsing at some frequency f_0 and "using AC-Coupling or Lock-In Amplification . . . to temporarily modulate the optical radiation of the LED at the carrier frequency f_0 in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶¶ 65, 69. Although Carlson gives a particular example of pulsing the LEDs at 1000 Hz, that example pertains to sampling pulsed LED light that has been transmitted through or reflected from a sample in the presence of 0 to 120 Hz noise. *Id.* ¶ 69. Carlson more generally teaches "shift[ing] the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely."

Dec. Inst. 34–35 (footnote in original).

Patent Owner disagrees with that preliminary analysis, arguing "Carlson does ***not*** disclose increasing a pulse rate of a light source to increase SNR as claimed." PO Resp. 17 (citing Ex. 2122 ¶ 84). Patent Owner's argument is two-fold. First, Patent Owner argues that Carlson only teaches "modulating the light source at a chosen single, fixed pulse rate, not ***increasing*** the pulse rate." PO Resp. 17 (citing Ex. 2122 ¶ 79). Second, Patent Owner argues switching "from an ***unmodulated*** light source to a temporary modulated light source at a chosen, unvarying pulse rate" does not teach "increasing [the light source's] pulse rate." PO Sur-Reply 13.

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the frequency of alternating periods of sunshine and shade, rather than to the actual frequency spectrum of sunlight, which is quite broad. The frequency spectrum of alternating periods of sunshine and shade would be 0 Hz when a person is standing in continual sunshine or continual shade, but would increase when travelling down a tree-lined street based on the spacing between trees and the speed of travel. *Id.* ¶ 68.

Petitioner replies that Carlson teaches "increasing the SNR of a pulsoximeter to improve its performance in the presence of noise, such as ambient light." Pet. Reply 13 (citing Pet. 23–24; Ex. 1009 ¶ 2). Petitioner argues that Carlson's "device is designed to address ***changing*** environmental conditions" because Carlson teaches "the amount of ambient light varies over time." *Id.* (citing Ex. 1009 ¶ 7). For example, Carlson teaches its "device '***temporarily*** modulate[s] the amplitude of the optical radiation of, e.g., the LED at a carrier frequency f_c in order ***to shift the power spectrum*** of the pulsoximeter signals ***into a higher frequency range*** where environmental optical radiation is unlikely." *Id.* at 14 (citing Ex. 1009 ¶ 20). Petitioner interprets this to mean the "device will change how its LEDs pulse based on the presence and characteristics of ambient light at any particular moment in time," and will do so by "shifting the frequency of an LEDs emission 'to a higher frequency range.'" *Id.*

Petitioner argues its interpretation of Carlson is supported by claims 10–13 of Carlson, which recite "a light source amplitude modulating means to modulate the frequency of the emitted light" that can "***shift the frequency*** of the emitted light." *Id.* at 15 (citing Ex. 1009, 6[10] (claims 10–13)). Moreover, Petitioner argues that "[b]ecause the nature of ambient light changes over time, it would be natural to interpret Carlson as describing multiple pulse frequencies." *Id.* at 16. Petitioner cites the testimony of Dr. MacFarlane, Patent Owner's expert, to support this contention. *Id.* According to Dr. MacFarlane, "[b]ecause sunlight variations and the weather

[10] The citation here is to Carlson's page number and claim number because the claims do not have separately numbered paragraphs.

are constantly changing environmental conditions, it would be impractical, as a matter of common sense, to have the user manually reconfigure the LED pulse rate as conditions change." Ex. 1060, 34:5–35:7.

Patent Owner argues we should ignore claims 10–13 of Carlson because Petitioner "never made this argument in its Petition." PO Sur-Reply 14. Patent Owner further argues we should ignore Dr. MacFarlane's "common sense" testimony because Petitioner "presented no 'common sense' argument in its Petition." *Id.* at 15.

As an initial matter, I disagree that the evidence presented in Petitioner's Reply should be ignored. Petitioner argued—*in the Petition*—that Carlson teaches increasing the pulse rate of an LED. *See* Pet. 38 ("Figure 8 of Carlson shows increasing the operating frequency F_0 of the LEDs as compared to Fig. 7c," and "[t]his frequency shift . . . corresponds to increasing the '*pulse rate*' of the emitter" LEDs). Although Petitioner supports this argument with new evidence in its Reply, the Reply does not raise a new issue or argument. *See Chamberlain Group, Inc. v. One World Techs., Inc.*, 944 F.3d 919, 925 (Fed. Cir. 2019) ("Parties are not barred from elaborating on their arguments on issues previously raised."). Moreover, the new evidence cited in Petitioner's Reply can be considered because Patent Owner had an adequate opportunity to address it in its Sur-Reply. *See In re NuVasive, Inc.*, 841 F.3d 966, 972 (Fed. Cir. 2016) (finding "an opportunity to respond was needed when the petitioner . . . newly pointed to a previously unmentioned portion of the . . . prior-art patent, even though it had earlier focused extensively on other portions of that prior-art patent").

Upon consideration of all the evidence and argument presented by Petitioner and Patent Owner, discussed above, I am persuaded that a person

of ordinary skill in the art would have understood Carlson to teach a light source configured to increase signal-to-noise in the presence of changing environmental conditions by increasing the modulation frequency or pulse rate of the light source. I disagree with Patent Owner's contention that Carlson only chooses a "fixed" or "predetermined" value for the LED pulse rate or modulation frequency at design-time. *See* PO Resp. 17–27, PO Sur-Reply 11–13. The only evidence Patent Owner offers for this contention is Carlson's statement that the modulation frequency is "chosen," and Dr. MacFarlane's opinion that this means a "fixed" value for the modulation frequency is chosen at design-time. *Id.*; *see also* Ex. 2122 ¶¶ 75–79. This evidence is unpersuasive for two reasons. First, Carlson does not expressly disclose choosing a "fixed" modulation frequency at design-time. Second, Dr. MacFarlane's testimony to that effect is not credible in view of Dr. MacFarlane's testimony regarding how a person skilled in the art would design a light source for use in changing lighting conditions.

Carlson's only teaching about choosing the modulation frequency of the light source is the following: "[I]t is therefore proposed to emit light by the LEDs not as current or continuous light but as pulsed light. The [pulse] frequency is chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light which, according to FIG 7b, is in the range of above approximately 1000 Hz." Ex. 1009 ¶ 69. Although this passage of Carlson teaches choosing a 1000 Hz pulse rate or modulation frequency, that choice is based on the specific power spectrum of the environmental optical radiation that is shown in Figure 7b. *Id.* But Carlson does not teach that the power spectrum shown in Figure 7b is fixed. To the contrary, Carlson teaches "[t]he power spectrum of environmental optical radiation *strongly*

varies as a function o[f] time and place where the pulsoximeter is used." *Id.* ¶ 7 (emphasis added). Thus, a person skilled in the art would read Carlson as choosing an appropriate modulation frequency at run-time based on the power spectrum of the environmental optical radiation existing at run-time. That is, a person skilled in the art would read Carlson to teach choosing a modulation frequency at *run-time* that "shift[s] the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely" because the "power spectrum of [the] environmental optical radiation *strongly* varies as a function o[f] time and place where the pulsoximeter is used," i.e., as a function of run-time values of time and place. *Id.* ¶¶ 7, 65 (emphasis added).

Carlson's claims support this interpretation. Claim 10 recites a "light source modulating means to *shift the frequency* of the emitted light." *Id.* at 6 (emphasis added). Claim 11 recites "a light source amplitude modulating means to *modulate the frequency of the emitted light in a frequency range* substantially outside of [the] frequency of noise and/or environmental signals." *Id.* (emphasis added). Given Carlson's teachings that the frequency spectrum of the environmental optical radiation *strongly* depends on the time and place where the pulsoximeter is used (i.e., *run-time* conditions), claims 10 and 11 teach a person skilled in the art that Carlson's modulation frequency f_c or pulse rate is "chosen" at run-time to allow the device to operate outside the frequency range of the power spectrum of the environmental optical radiation that exists at run-time, and that the pulse rate can be "shifted" to allow the device to continue to operate outside the frequency range of that power spectrum as that frequency range varies with the time and place of pulsoximeter use. *Id.* ¶¶ 7, 65; *id.* at 6 (claims 10, 11).

In fact, in the course of explaining how the light source in the '533 patent "achieve[s] higher SNR despite 'variations due to sunlight' and the 'effects of weather, such as clouds and rain,'" Dr. MacFarlane provides a coherent explanation of *why* a person skilled in the art would read Carlson to teach choosing a suitable pulse rate or modulation frequency at run-time rather than a fixed pulse rate or modulation frequency at design-time. Ex. 2122 ¶ 36. According to Dr. MacFarlane, the light source disclosed in the '533 patent increases signal-to-noise by increasing its pulse rate or modulation frequency "[b]ecause sunlight variations and the weather are *constantly changing environmental conditions*, [and] it would be impractical—as a matter of common sense—to have the user manually reconfigure the LED pulse rate as conditions change to achieve higher SNR." *Id.* (emphasis added). Dr. MacFarlane testifies that a person skilled in the art would never "ask[] a consumer to learn what SNR is and force that consumer to -- adjust it as a cloud moves across the sun and then back again." Ex. 1060, 36:1–7. That, Dr. MacFarlane says, "would be impractical and not a very nice product design to -- to -- to force your user to do that. And that seems -- that seems a matter of common sense, to me, but, again, that's from the perspective of a person of ordinary skill in the art." *Id.* at 36:9–13.

To understand why this testimony supports Petitioner's interpretation of Carlson, it is necessary to first explore how Dr. MacFarlane finds support for the pulse rate limitation in columns 5, 16, 19, and 20 of the '533 patent, and two publications incorporated into the '533 patent in column 1. *See* Ex. 2121 ¶¶ 24–25, 35–36 (citing Ex. 1001, 1:33–37, 1:40–42, 5:11–15, 16:54–58, 19:67–20:2; Ex. 2120 ¶ 79; Ex. 2121 ¶ 45). As discussed in § II.D.3 of

the panel decision, the passage in column 5 of the '533 patent identically supports the pulse rate limitation because it repeats it verbatim. *Compare* Ex. 1001, 5:11–15, *with id.* at 30:56–60. It does not, however, illuminate the meaning of the limitation because the passage was added to the Specification at the same time the limitation was added to then pending claim 14, which issued as claim 13, and no explanation was provided to indicate how the originally filed Specification supports the limitation. *See* Ex. 1002, 495–496, 502–503, 505–507.

The remaining passages cited by Dr. MacFarlane do not illuminate the meaning of the pulse rate limitation because they do not disclose a light source configured to increase signal-to-noise by increasing its pulse rate. For example, although the passage from column 19, line 67 to column 20, line 2 states that LEDs can be operated in "continuous wave or pulsed mode," it does not state that the pulse rate can be increased to increase signal-to-noise.[11] Ex. 1001, 19:67–20:2. Similarly, although the passage in the PCT publication incorporated by reference in column 1[12] states the "active illuminator" achieves high signal-to-noise using "modulation and lock-in techniques" whereby "the light source may be modulated, and then the detection system would be synchronized with the light source," it does not state that signal-to-noise is increased by increasing the modulation

[11] Carlson also discloses that LEDs can be operated in either continuous or pulsed mode. *See* Ex. 1009 ¶ 69 (proposing to emit LED light "not as current or continuous light but as pulsed light").

[12] This disclosure is nearly identical to the disclosure in the '533 patent. *Compare* Ex. 2120 ¶ 75 *with* Ex. 1001, 16:54–65.

frequency or pulse rate of the light source.[13] Ex. 2120 ¶ 75. Likewise, although the passage in the published patent application incorporated by reference in column 1 states "continuous-wave systems emit light at approximately constant intensity or modulated at low frequencies, such as 0.1–100 kHz," it does not state that the modulation frequency or pulse rate of the light source is increased to increase signal-to-noise.[14] Ex. 2121 ¶ 45. In sum, to conclude the '533 patent's "active illuminator" increases signal-to-noise by increasing its pulse rate, Dr. MacFarlane ultimately relies on the "common sense" and knowledge of a person of ordinary skill in the art rather than on any actual disclosure in the '533 patent.

As discussed above, Carlson also teaches that sunlight and ambient light can interfere with a pulsoximeter signal in a manner that varies with time and place, and that the resulting interference can be reduced to increase signal-to-noise by modulating the pulsoximeter's LED. *See* Ex, 1009 ¶¶ 2, 7, 65, 67. For example, Carlson is "particularly concerned with increasing the technical performance of pulsoximetry in terms of quality and robustness of the measurement signal versus environmental disturbances." Ex. 1009 ¶ 2. Carlson teaches the modulation "frequencies of sunlight and ambient

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[13] Carlson also discloses increasing signal-to-noise by "using AC-Coupling or Lock-In Amplification (synchronous detection) to temporarily modulate the optical radiation of the LED." Ex. 1009 ¶¶ 65, 69. According to Carlson, lock-in detection techniques are "well known out of the state of the art." *Id.* ¶ 65.

[14] Carlson also discloses that LEDs can be pulsed at different pulse rates. *See* Ex. 1009 ¶ 69 (disclosing the LED pulse rate "F_0 could be e.g., as mentioned, 1000 Hz" or "can be chosen at any other frequency, as e.g. 2000 Hz or even higher.").

light" are sources of interference because they are within "the range of frequencies of physiological signals." *Id.* ¶ 67. Carlson teaches "[t]he power spectrum of [this] environmental optical radiation *strongly varies* as a function o[f] time and place where the pulsoximeter is used." *Id.* ¶ 7 (emphasis added). This strong variation means the "detected optical power varies in a large [frequency] range, making difficult the analog and digital signal processing of the primary sensor signal." *Id.* Carlson's solution is to "temporarily modulate the . . . LED at the carrier frequency f_c in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶ 65. Carlson does this by choosing modulation frequency f_c "in such a way that it is outside the frequency spectrum of sunlight and ambient light" using a light source modulating means that "shift[s] the frequency of the emitted light" and "modulate[s] the frequency of the emitted light in a frequency range substantially outside of the frequency of noise and/or environmental signals." *Id.* ¶ 69 (emphasis added); *id.* at 6 (claims 10, 11).

Yet, despite all of Carlson's teachings about the variable nature of the interference caused by sunlight and how that interference can be reduced by modulating the LEDs at a pulse rate or modulation frequency that exceeds the varying frequency spectrum of the interference, and despite Dr. MacFarlane's testimony that a person skilled in the art would never "ask[] a consumer to learn what SNR is and force that consumer to -- adjust it as a cloud moves across the sun and then back again," Dr. MacFarlane opines that a person skilled in the art would read Carlson as choosing a "fixed" pulse rate at design-time rather than a "suitable" pulse rate at run-time that reduces the actual interference seen at run-time. *See* Ex. 1060, 36:1–7l; *see*

also Ex. 2122 ¶¶ 75–79. That is, Dr. MacFarlane opines that a person skilled in the art would read Carlson to teach choosing a "fixed" pulse rate at design-time that either will or will not improve signal-to-noise because it either will or will not shift the pulsoximeter power spectrum beyond the power spectrum of the run-time environmental noise. This is not a credible reading of Carlson. A more credible reading is that a person skilled in the art would read Carlson to teach choosing a suitable pulse rate at run-time that *will* improve the signal-to-noise ratio because it *will* shift the pulsoximeter power spectrum beyond the power spectrum of the run-time environmental noise. Moreover, Carlson's pulsoximeter will update its choice of pulse rate during operation, as needed, as the power spectrum of the environmental noise varies with the time and place of the pulsoximeter's use, e.g., by increasing the LED pulse rate.

In addition to disagreeing with Patent Owner's contention that Carlson only teaches switching from continuous light to light modulated at 1000 Hz for the reasons explained above, I also disagree with Patent Owner's contention that such switching does not increase the pulse rate of the light source. Implicit in Patent Owner's argument is the assumption that a light source emitting continuous light does not have a pulse rate or modulation frequency that can be increased. This assumption is contrary to the teachings of Carlson.

Figure 7b of Carlson is reproduced below.

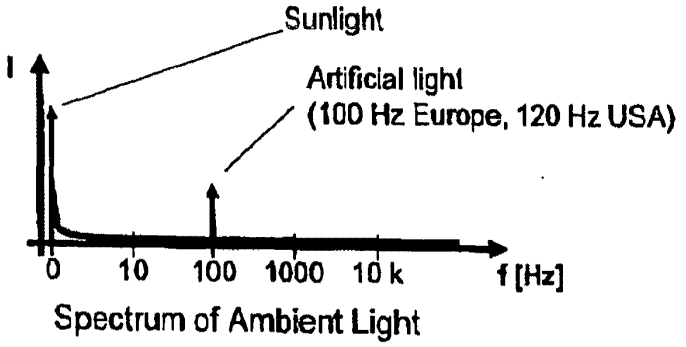


Figure 7b is "a diagram showing [the] power spectrum of ambient light." Ex. 1009 ¶ 43. In the exemplary power spectrum shown in Figure 7b, the noise contribution due to "[s]unlight is 0 Hz." *Id.* ¶ 67, Fig. 7b. The power spectrum shown in Figure 7b is exemplary because Carlson more generally teaches the noise contribution due to sunlight depends on its modulation frequency, i.e., how frequently a pulsoximeter experiences alternating periods of sunlight and shade. *See id.* ¶ 68 ("Another serious possibility is caused by a tree avenue when driving along the trees. Sunlight is then received, e.g., by the pulsoximeter sensor at *a certain frequency*, which means that every time when passing a tree, sunlight is attenuated and between trees sunlight is influencing the measurement of the pulsoximetric sensor.") (emphasis added).

In our Institution Decision, we made a preliminary finding that Figure 7b of Carlson teaches sunlight contributes noise at 0 Hz when pulsoximeter measurements are taken in either continuous sunshine or continuous shade. *See* Dec. Inst. 34, n.7 ("The *frequency spectrum* of alternating periods of sunshine and shade *would be 0 Hz* when a person is standing *in continual sunshine or continual shade, but would increase when travelling down a*

tree-lined street based on the spacing between trees and the speed of travel.") (emphases added). Patent Owner does not dispute this finding, despite having had two opportunities to do so. *See* PO Resp. 14–32; PO Sur-Reply 11–16. Carlson's teaching that continuous sunlight contributes noise at a frequency of 0 Hz is a teaching that continuous sunlight has a modulation frequency of 0 Hz, i.e., that it is not modulated or that its intensity does not periodically vary between sunshine and shade. That is, Carlson teaches that continuous light has a modulation frequency or pulse rate of 0 Hz. Therefore, even under Patent Owner's narrow interpretation of Carlson, in which Carlson increases signal-to-noise by switching from emitting continuous light to emitting light modulated at 1000 Hz, Carlson teaches increasing signal-to-noise by increasing the modulation frequency or pulse rate of the light source from 0 Hz to 1000 Hz.

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NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

OMNI MEDSCI, INC.,
Appellant

v.

APPLE INC.,
Appellee

2021-1229

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-00916.

JUDGMENT

THOMAS A. LEWRY, Brooks Kushman PC, Southfield, MI, argued for appellant. Also represented by JOHN S. LEROY, CHRISTOPHER C. SMITH.

JEFFREY PAUL KUSHAN, Sidley Austin LLP, Washington, DC, argued for appellee. Also represented by THOMAS ANTHONY BROUGHAN, III, JOSHUA JOHN FOUGERE; CHING-LEE FUKUDA, New York, NY; MICHAEL ROBERTS, Dallas, TX.

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (MOORE, *Chief Judge*, DYK and CHEN, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

June 8, 2022
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

United States Court of Appeals for the Federal Circuit

OMNI MEDSCI, INC.,
Appellant

v.

APPLE INC.,
Appellee

2021-1229

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-00916.

MANDATE

In accordance with the judgment of this Court, entered June 8, 2022, and pursuant to Rule 41 of the Federal Rules of Appellate Procedure, the formal mandate is hereby issued.

FOR THE COURT

July 15, 2022
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

(12) **INTER PARTES REVIEW CERTIFICATE** (2907th)
United States Patent
Islam

(10) **Number: US 9,651,533 K1**
(45) **Certificate Issued: Nov. 9, 2022**

(54) **SHORT-WAVE INFRARED SUPER-CONTINUUM LASERS FOR DETECTING COUNTERFEIT OR ILLICIT DRUGS AND PHARMACEUTICAL PROCESS CONTROL**

(71) Applicant: **OMNI MEDSCI, INC.**

(72) Inventor: **Mohammed N. Islam**

(73) Assignee: **Omni Medsci, Inc.**

Trial Number:

IPR2019-00916 filed Apr. 10, 2019

Inter Partes Review Certificate for:

Patent No.: **9,651,533**
Issued: **May 16, 2017**
Appl. No.: **14/875,709**
Filed: **Oct. 6, 2015**

The results of IPR2019-00916 are reflected in this inter partes review certificate under 35 U.S.C. 318(b).

AS A RESULT OF THE INTER PARTES REVIEW PROCEEDING, IT HAS BEEN DETERMINED THAT:

Claims **5**, **7-10**, **13** and **15-17** are cancelled.

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