Appeal decision

Appeal No. 2014- 5608

USA
Appellant CAS MEDICAL SYSTEMS INC.

Tokyo, Japan
Patent Attorney KINUTANI, Nobuo

The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2009-287908, entitled "NEAR INFRARED SPECTROPHOTOMETRIC SENSOR" (the application published on April 22, 2010, Japanese Unexamined Patent Application Publication No. 2010- 88928) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The application was filed on July 24, 2003 (priority claim under the Paris Convention dated July 26, 2002, dated August 30, 2002 in US) as Japanese Patent Application No. 2004-524717, and a part thereof was filed on December 18, 2009 as a new patent application. The reason for refusal was notified on January 11, 2012, and a written opinion was submitted and an amendment was made on June 18, 2012. The final reason for refusal was notified on January 28, 2013, and a written opinion was submitted and an amendment was made on March 18, 2013. The examiner's decision to dismiss amendment was made and the decision of refusal was issued on November 18, 2013, and an appeal against the examiner's decision of refusal was requested and the amendment was made on March 26, 2014. The reason for refusal was notified on April 21, 2015 by the body, and a written opinion was submitted and an amendment was made on September 15, 2015.

No. 2 The Invention

The inventions according to Claims 1 to 4 of the application are recognized as inventions specified by matters described in Claims 1 to 4 of the claims amended with an amendment dated September 15, 2015, and the invention according to Claim 1 (hereinafter referred to as "the Invention") is as follows.

"A near infrared spectrophotometric sensor for determining a blood oxygen saturation degree within a subject's tissue comprising:

a light source configured to transmit a light signal including light of a first wavelength, light of a second wavelength, and light of a third wavelength to propagate into the subject's tissue;

two light detectors configured to individually detect first light intensity and second light intensity with respect to light of the first wavelength, light of the second wavelength, and light of the third wavelength at positions on a same straight line of a first predetermined distance and a second predetermined distance after the light signal propagates into the subject's tissue; and

a processing part configured to determine the blood oxygen saturation level within the subject's tissue by reference to a calibration constant, the calibration constant being determined by reference to a difference in attenuation between the light of the first wavelength and the light of the second wavelength, a difference in attenuation between the light of the first wavelength and the light of the third wavelength, and empirical data developed from the subject's tissue, the difference in attenuation between the light of the first wavelength and the light of the second wavelength being determined by reference to attenuation of the light of the first wavelength and attenuation of the light of the second wavelength, the difference in attenuation between the light of the first wavelength and the light of the third wavelength being determined by reference to attenuation of the light of the first wavelength and attenuation of the light of the third wavelength, the attenuation of the light of the first wavelength being determined by reference to the first light intensity and the second light intensity of light of the first wavelength, the attenuation of the light of the second wavelength being determined by reference to the first light intensity and the second light intensity of light of the second wavelength, and the attenuation of the light of the third wavelength being determined by reference to the first light intensity and the second light intensity of light of the third wavelength,

wherein the processing part is calibrated in advance by reference to a calibration constant determined by reference to a vein oxygen saturation level and an artery oxygen saturation level, and the vein oxygen saturation level and the artery oxygen saturation level are determined by reference to the empirical data obtained by individually sampling or continuously monitoring blood within the subject's tissue while detecting the subject's tissue with the near infrared spectrophotometric sensor."

No. 3 Notice of reasons for refusal of the body

The outline of the reasons for refusal of the body is as follows.

Since the inventions according to Claims 1 to 6 of the application could have been easily made by a person skilled in the art based on the Invention in the cited document distributed before the priority date of the application and the well-known arts, the appellant should not be granted a patent under the provisions of Article 29(2) of the Patent Act.

No. 4 Described matters of Cited Document

1 In International Publication No. WO 01/084107 (hereinafter, referred to as "the Cited Document") distributed before the priority date of the application and cited for the reasons for refusal of the body, the following matters are described with drawings. (A Japanese translation of the Cited Document is described. The translation is based on National Publication of International Patent Application No. 2003-532107, which is a corresponding Japanese publication, and paragraph numbers are also described. Underlines are added by the body.).

(1) Claims 14, 15, and 16 of Cited Document

("14. A method for determining a blood oxygen saturation level within a subject's tissue using a near infrared spectrophotometric sensor attached to the skin of the subject, said method comprising the steps of:

transmitting a light signal into the subject's tissue at a predetermined first intensity, wherein the transmitted light signal includes a first wavelength, a second wavelength, and a third wavelength;

sensing a second intensity of the light signal of the first, second, and third wavelengths after the light signal travels through the subject;

determining an attenuation of the light signal for each of the first, second, and third wavelengths by reference to the predetermined first intensity and the sensed second intensity of the first, second, and third wavelengths;

determining a difference in attenuation of the light signal between the first wavelength and the second wavelength, and between the first wavelength and the third wavelength;

determining a first calibration constant and a second calibration constant by reference to empirical data developed from the subject at or about the same time as when the sensing occurs; and

determining the blood oxygen saturation level within the subject's tissue by reference to the difference in attenuation between the first wavelength and the second wavelength, and the difference in attenuation between the first wavelength and the third wavelength, and the first calibration constant and the second calibration constant.

15. The method of claim 14 wherein the empirical data are collected by discretely sampling a venous blood source and an arterial blood source from the subject.

16. The method of claim 14 wherein the empirical data are collected by continuously monitoring a venous blood source and an arterial blood source from the subject.")

(2) Paragraphs [0029] to [0030] of Cited Document

("[0025]

Referring to FIGS. 1-5, the preferred NIRS sensor includes a transducer portion 10 and a processor portion 12. The transducer portion 10 includes an assembly housing 14 and a connector housing 16. The assembly housing 14, which is a flexible structure that can be attached directly to a subject's body, includes one or more light sources 18 and a light detector 20 (Note by the body: "Hikari kenchiki 20" and "Hikari kenshutuki 20" have the same meaning. The same applies hereafter.). A disposable adhesive envelope or pad is used for mounting the assembly housing 14 easily and securely to the subject's skin. Light signals of known but different wavelengths from the light sources 18 are emitted through a prism assembly 22. The light sources 18 are preferably laser diodes that emit light at a narrow spectral bandwidth at predetermined wavelengths. In one embodiment, the laser diodes are mounted within the connector housing 16. The laser diodes are optically interfaced with a fiber optic light guide to the prism assembly 22 that is disposed within the assembly housing 14. In a second embodiment, the light sources 18 are mounted within the assembly housing 14. A first connector cable 26 connects the assembly housing 14 to the connector housing 16 and a second connector cable 28 connects the connector housing 16 to the processor portion 12. The light detector 20 includes one or more photodiodes. The photodiodes are also operably connected to the processor portion 12 via the first and second connector cables 26, 28. The processor portion 12 includes a processor for processing light intensity signals from the light sources 18 and the light detector 20.

[0026]

The processor utilizes an algorithm that characterizes a change in attenuation as a function of the difference in attenuation between different wavelengths. The present method advantageously accounts for but minimizes the attenuation effects of the scattering variable "G," pathlength B*d, and the absorption "F" due to other components present in biological tissue (i.e. bone, water, skin, pigmentation, etc.) that have a relatively flat or very low absorption spectra over the measured wavelength range. In addition, the present method accounts for any offset attenuation "N" due to the characteristics of the sensor that may or may not be wavelength independent. The present method algorithm can be expressed as:

$A\lambda 1-A\lambda 2=\Delta A\lambda 1-\lambda 2=\Delta A\lambda 12$ (5)

where $A\lambda 1$ and $A\lambda 2$ are in the form of Equation 6 below, which is a modified version of Equation 2 that accounts for attenuation due to "F" and "N":

$A\lambda=-\log(I/Io)\lambda=\alpha\lambda * c * d * B\lambda+G+F+N$ (6)

Substituting Equation 6 into Equation 5 for $A\lambda 1$ and $A\lambda 2$, the terms "F" and "N" within Equation 5 are subtracted out, provided they represent constant light absorption over the measurement wavelengths and provided the same sensor is used to sense the light signal at the various wavelengths. Therefore, in the case where the differential pathlength factor B is wavelength independent, $\Delta A\lambda 12$ can be expressed as:

$\Delta A\lambda 12=\log[(I\lambda 1/Io\lambda 1)*(I\lambda 2/Io\lambda 2)]=\Delta\alpha c\lambda 12cdB+\Delta G\lambda 12$ (7)

and rewritten in expanded form:

$\Delta A\lambda 12=(\alpha Hb\lambda 1-\alpha Hb\lambda 2)[Hb]dB+(\alpha HbO2\lambda 1-\alpha HbO2\lambda 2)[HbO2]dB+\Delta G\lambda 12$ (8). ")

(3) It is readily apparent and obvious that, in (1) described above, "transmitting a light signal" "including the first wavelength, the second wavelength," and "the third wavelength" "into the subject's tissue at a predetermined first intensity" is performed by "the light source" in (2) described above.

(4) It is readily apparent and obvious that, in (1) described above, "sensing a second intensity of the light signal of the first, second, and third wavelengths after the light signal travels through the subject" is performed by "the light detector" of (2) described above.

(5) It is readily apparent and obvious that, in (1) described above, each step of "determining an attenuation of the light signal for each of the first, second, and third

wavelengths using the predetermined first intensity and the sensed second intensity of the first, second, and third wavelengths; determining a difference in attenuation of the light signal between the first wavelength and the second wavelength, and between the first wavelength and the third wavelength; determining a first calibration constant and a second calibration constant using empirical data developed from the subject at or about the same time as when the sensing occurs; and determining the blood oxygen saturation level within the subject's tissue by reference to the difference in attenuation between the first wavelength and the second wavelength, and the difference in attenuation between the first wavelength and the third wavelength, and the first calibration constant and the second calibration constant" is performed by "the processor" in (2) described above.

From (1) to (5) above, it is recognized that the Cited Document describes the following invention.

"A near infrared spectrophotometric sensor for determining a blood oxygen saturation level within a subject's tissue comprising:

a light source configured to transmit a light signal including a first wavelength, a second wavelength, and a third wavelength into the subject's tissue by reference to a predetermined first intensity;

a light detector configured to detect second intensity of light signal of the first wavelength, the second wavelength, and the third wavelength after the light signal is transmitted through the subject; and

a processor configured to determine the blood oxygen saturation level within the subject's tissue by reference to a difference in attenuation between the first wavelength and the second wavelength, a difference in attenuation between the first wavelength and the third wavelength, a first calibration constant, and a second calibration constant, the processor being configured to, by reference to a predetermined first intensity and detected second intensity of the first wavelength, the second wavelength, and the third wavelength, determine attenuation of each of the light signals of the first, second, and third wavelengths, determine a difference in attenuation of light signals between the first wavelength and the second wavelength and a difference in attenuation of light signals between the first wavelength and the third wavelength, and determine a first calibration constant and a second calibration constant by reference to empirical data developed at or about the same time as when the sensing occurs,

wherein the empirical data are collected by discretely sampling a venous blood source and an arterial blood source from the subject or collected by continuously monitoring a venous blood source and an arterial blood source from the subject." (hereinafter, referred to as "the Cited Invention").

No. 5 Comparison / judgment

The Invention and the Cited Invention are compared.

1 "A near infrared spectrophotometric sensor for determining a blood oxygen saturation level within a subject's tissue " of the Cited Invention corresponds to "a near infrared spectrophotometric sensor for determining a blood oxygen saturation degree within a subject's tissue" of the Invention.

2 " A light source configured to transmit a light signal including a first wavelength, a second wavelength, and a third wavelength into the subject's tissue" of the Cited Invention corresponds to "a light source configured to transmit a light signal including light of a first wavelength, light of a second wavelength, and light of a third wavelength to propagate into the subject's tissue" of the Invention.

3 " A light detector configured to detect second intensity of light signal of the first wavelength, the second wavelength, and the third wavelength after the light signal is transmitted through the subject" of the Cited Invention and "two light detectors configured to individually detect first light intensity and second light intensity with respect to light of the first wavelength, light of the second wavelength, and light of the third wavelength at positions on a same straight line of a first predetermined distance and of a second predetermined distance after the light signal propagates into the subject's tissue" of the Invention are common to the point of "a light detector configured to detect second light intensity with respect to light of the first wavelength, light of the second wavelength, and light of the third wavelength at a position of a predetermined distance after the light signal propagates into the subject's tissue."

4 " A processor configured to determine the blood oxygen saturation level within the subject's tissue by reference to a first calibration constant and a second calibration constant" of the Cited Invention corresponds to "a processing part configured to determine the blood oxygen saturation level within the subject's tissue by reference to a calibration constant" of the Invention.

5 Since "determining a first calibration constant and a second calibration constant using

empirical data developed from the subject at or about the same time as when the sensing occurs" is performed through "determining a difference in attenuation between the first wavelength and the second wavelength, and between the first wavelength and the third wavelength," the configuration of the Cited Invention corresponds to "the calibration constant being determined by reference to a difference in attenuation between the light of the first wavelength and the light of the second wavelength, a difference in attenuation between the light of the first wavelength and the light of the third wavelength, and empirical data developed from the subject's tissue" of the Invention.

6 "By reference to a predetermined first intensity and detected second intensity of the first wavelength, the second wavelength, and the third wavelength, determine attenuation of each of the light signals of the first, second, and third wavelengths, determine a difference in attenuation of light signals between the first wavelength and the second wavelength and a difference in attenuation of light signals between the first wavelength and the third wavelength" of the Cited Invention corresponds to "the difference in attenuation between the light of the first wavelength and the light of the second wavelength being determined by reference to attenuation of the light of the first wavelength and attenuation of the light of the second wavelength, the difference in attenuation between the light of the first wavelength and the light of the third wavelength being determined by reference to attenuation of the light of the first wavelength and attenuation of the light of the third wavelength, the attenuation of the light of the first wavelength being determined by reference to the first light intensity and the second light intensity of light of the first wavelength, the attenuation of the light of the second wavelength being determined by reference to the first light intensity and the second light intensity of light of the second wavelength, and the attenuation of the light of the third wavelength being determined by reference to the first light intensity and the second light intensity of light of the third wavelength" of the Invention.

7 It is readily apparent and obvious that before "a processor" "determines the blood oxygen saturation level within the subject's tissue," calibration is performed in advance "by reference to the first calibration constant and the second calibration constant."

Therefore, this obvious configuration and that "a processor" of the Cited Invention, when "determining a first calibration constant and a second calibration constant by reference to empirical data developed from the subject at or about the same time as when the sensing occurs," "the empirical data are collected by discretely sampling a venous blood source and an arterial blood source from the subject or collected by continuously monitoring a venous blood source and an arterial blood source from the subject" correspond to that "the processing part is calibrated in advance by reference to a calibration constant determined by reference to a vein oxygen saturation level and an artery oxygen saturation level, and the vein oxygen saturation level and the artery oxygen saturation level are determined by reference to the empirical data obtained by individually sampling or continuously monitoring blood within the subject's tissue while detecting the subject's tissue with the near infrared spectrophotometric sensor" of the Invention.

Therefore, the Invention and the Cited Invention are common in the point that

"A near infrared spectrophotometric sensor for determining a blood oxygen saturation degree within a subject's tissue comprising:

a light source configured to transmit a light signal including light of a first wavelength, light of a second wavelength, and light of a third wavelength to propagate into the subject's tissue;

a light detector configured to detect second light intensity with respect to light of the first wavelength, light of the second wavelength, and light of the third wavelength at a predetermined distance after the light signal propagates into the subject's tissue; and

a processing part configured to determine the blood oxygen saturation level within the subject's tissue by reference to a calibration constant, the calibration constant being determined by reference to a difference in attenuation between the light of the first wavelength and the light of the second wavelength, a difference in attenuation between the light of the first wavelength and the light of the third wavelength, and empirical data developed from the subject's tissue, the difference in attenuation between the light of the first wavelength and the light of the second wavelength being determined by reference to attenuation of the light of the first wavelength and attenuation of the light of the second wavelength, the difference in attenuation between the light of the first wavelength and the light of the third wavelength being determined by reference to attenuation of the light of the first wavelength and attenuation of the light of the third wavelength, the attenuation of the light of the first wavelength being determined by reference to the first light intensity and the second light intensity of light the first wavelength, the attenuation of the light of the second wavelength being determined by reference to the first light intensity and the second light intensity of light the second wavelength, and the attenuation of the light of the third wavelength being determined by reference to the first light intensity and the second light intensity of light of the third wavelength, wherein the processing part is calibrated in advance by reference to a calibration constant determined by reference to a vein oxygen saturation level and an artery oxygen saturation level, and the vein oxygen saturation level and the artery oxygen saturation level are determined by reference to the empirical data obtained by individually sampling or continuously monitoring blood within the subject's tissue while detecting the subject's tissue with the near infrared spectrophotometric sensor", and differ in the following points.

(The different feature 1)

Regarding "a light detector configured to detect second light intensity with respect to light of the first wavelength, light of the second wavelength, and light of the third wavelength at a position of a predetermined distance after the light signal propagates into the subject's tissue", it corresponds to "two light detectors configured to detect first light intensity and second light intensity" "at positions on a same straight line of a first predetermined distance and of a second predetermined distance individually" in the Invention, whereas it corresponds to one detector "configured to detect second light intensity" in the Cited Invention.

(The different feature 2)

Regarding first light intensity and second light intensity of light of the first to third wavelengths used for determining light attenuation of light of the first to third wavelengths, they correspond to "first light intensity and second light intensity" "detected" "with two detectors" "individually at positions at a first predetermined distance and a second predetermined distance positioned on a same straight line" in the Invention, whereas they correspond to "a predetermined first intensity" of "a light signal" "transmitted" "into the subject's tissue" and "second intensity of the light signal" "detected" "after the light signal transmits through the subject" in the Cited Invention.

(Regarding the different features 1, 2)

It is a well-known art as disclosed in paragraphs [0005] to [0006] of Japanese Examined Utility Model Registration Application Publication No. 3016160 cited for the reasons for refusal by the body, for instance, to calculate an oxygen saturation degree on the basis of a light reception signal passing through only the cerebral cortex, which is at a deep place, obtained by disposing light receiving elements at two places at different distances from a light source; acquiring a light reception signal at a deep place with a light receiving element placed at a long distance; acquiring a light reception signal near the skull, which is at a shallow place, with a light receiving element placed at a short distance; recognizing the light reception signal at a shallow place to be common; and subtracting the light reception signal at the shallow place from the light reception signal at the deep place, in order to detect with high accuracy a blood oxygen state of a cerebral cortex by extracting a signal corresponding to a deep place of the cerebral cortex.

Therefore, it can be said that it could have easily been arrived by a person skilled in the art to, in the Cited Invention, apply the well-known technology described above in an attempt to extract a signal corresponding to a deep place of a cerebral cortex from the intensity of a light signal, which is a light reception signal, and detect with high accuracy a blood oxygen state of the cerebral cortex; in other words, in place of "determining attenuation of a light signal" by reference to "a predetermined first intensity" of "the light signal" "transmitted" "into the subject's tissue with the predetermined first intensity" and "second intensity of the light signal" "detected" with "a light detector" "after the light signal transmits through the subject" of the Cited Invention, to obtain the intensity of a light signal passing through only the cerebral cortex, which is at a deep place, and, on the basis of the intensity of the light signal, determine an oxygen saturation level by disposing light receiving elements, which are a first light detector and a second light detector, at two places of different distances from a light source, which are a first predetermined distance and a second predetermined distance; acquiring second intensity of the light signal at a deep place with a second light detector at a long distance; acquiring first intensity of the light signal near the skull, which is at a shallow place, with a first light detector at a short distance; regarding the intensity of the light signal at the shallow place as common; and subtracting the first intensity of the light signal at the shallow place from the second intensity of the light signal at the deep place.

It can be said that it is a self-evident design matter to a person skilled in the art that it is preferable, in order to obtain the intensity of the light signal passing through only the cerebral cortex, which is at the deep place, by regarding the intensity of the light signal at the shallow place as common and subtracting the first intensity of the light signal at the shallow place from the second intensity of the light signal at the deep place, to dispose two light detectors on the same straight line so that the two light detectors can detect the intensity of light signals passing through almost the same route (near the skull), which is at the shallow place.

Concerning disposing two light detectors "on the same straight line," although the description itself is not in the specification of the present application, determination was made by considering the drawings attached to the present application and the description reading: "on the same straight line means, in the case of a curved surface (such as a surface of a human head), along a straight line drawn on the curved surface" of a written opinion dated on September 15, 2015.

(Effect)

The effect exerted by the Invention is within a range that can be predicted by a person skilled in the art from the Cited Invention and well-known arts and cannot be said to be remarkable.

Therefore, the Invention could have been easily invented by a person skilled in the art on the basis of the Cited Invention and well-known arts.

No. 6 Closing

As described above, the appellant should not be granted a patent for the Invention under the provisions of Article 29(2) of the Patent Act.

Therefore, the application shall be refused without examining the remaining claims.

Therefore, the appeal decision shall be made as described in the conclusion.

October 26, 2015

Chief administrative judge:	MISAKI, Hitoshi
Administrative judge:	FUJITA, Toshihiko
Administrative judge:	ASO, Tetsuo