

Patentable Subject Matter of Medical Treatment in Japan

Hitoshi MAEDA Patent Attorney

Rejected Claims (Methods)

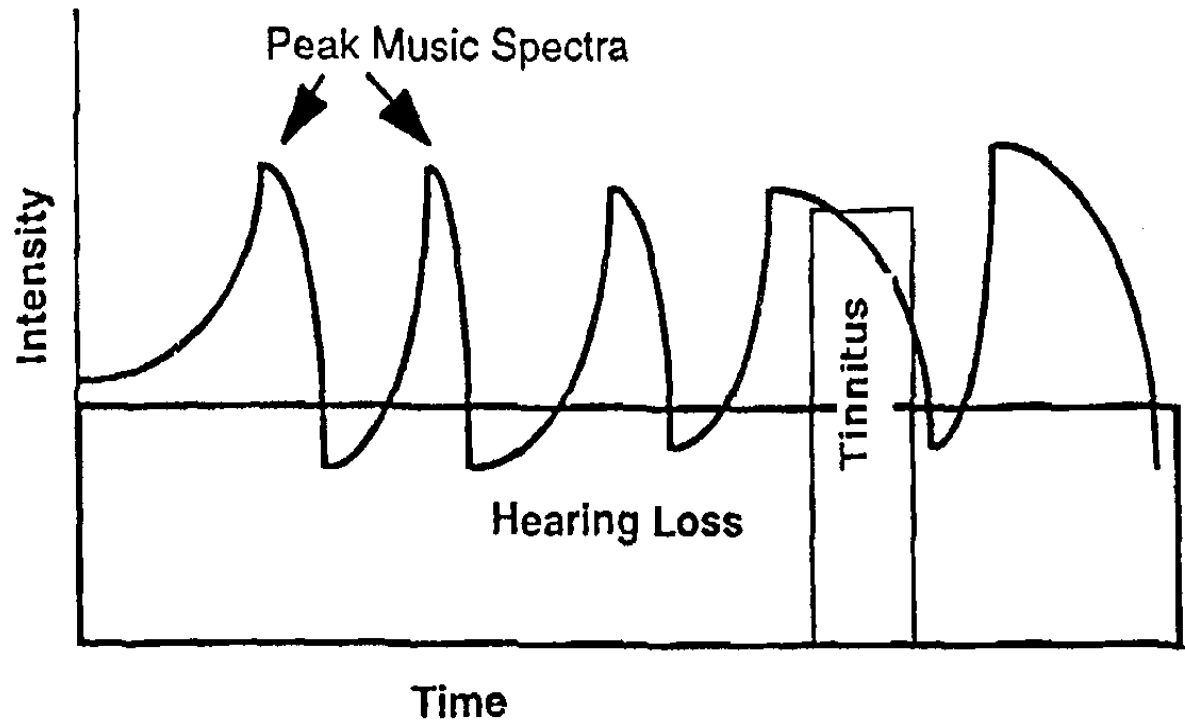
【Claim 1】

A tinnitus rehabilitation method for providing relief to a person suffering from the disturbing effects of tinnitus, the method comprising:

providing an audio signal spectrally modified in accordance with a predetermined masking algorithm designed to modify the intensity of the audio signal at selected frequencies,

whereby, in use, when the spectrally modified audio signal is heard by the person it provides significant masking of the tinnitus.

Abstract Representative Drawings



Notification of Reasons for Refusal

Japanese Patent Application No. 2000-605446

The present invention according to this application does not satisfy the requirements for provision of Patent Law Article 29(1). Therefore this application cannot be granted with a patent.

Remarks

The claims 1-11 according to the present invention regards to a tinnitus rehabilitation method for providing a relief to the persons suffering from the disturbing effects of tinnitus, which applies to “a method for curing human”.

Also, the claim 15 of the present invention comprises; step of receiving the data representing of the audiogram of the patient suffering from the tinnitus from the user through online; and step of sending the required equalization response data to the user. This applies to “a method for diagnosing human” and “a method for curing human”.

Thus, the claims 1-11 and 15 according to the present invention cannot be a industrially applicable, hence this does not apply to the invention stated on Patent Law Article 29(1).

First Amendments (Methods)

【Claim 1】

A method for producing an audio signal that provides a stimulus to the auditory system of an individual experiencing tinnitus or hyperacusis, the method comprising:

providing an audio signal including peaks and troughs;

producing a predetermined masking algorithm designed to modify the intensity of said audio signal at selected frequencies for providing intermittent masking of tinnitus based on a basic audiometric measurement information of the individual and to achieve a required equalization response for providing a comparative equal sensation level at every frequency; and

spectrally modifying the audio signal in accordance with the predetermined masking algorithm wherein, in use at a comfortable listening level, when the spectrally modified audio signal is heard by the individual during the peaks, the tinnitus is substantially completely obscured and the individual perceives significant masking of the tinnitus, and during the troughs, the individual may occasionally perceive the tinnitus.

Notification of Reasons for Refusal

<<< *FINAL* >>>

The present invention according to this application does not satisfy the requirements for provision of Patent Law Article 29(1). Therefore this application cannot be granted with a patent.

Remarks

The invention according to claims 1 to 8 and the invention according to claims 9 and 10 include a medical act practiced by person. Thus said invention is not deemed as the application method of medical devices.

Therefore the invention according to claims 1 to 10 is not industrially applicable, hence said invention does not apply to invention described in Article 29(1), thereby the invention is not entitle to obtain a patent.

< Suggestion for the amendments >

In regards with claims 1 and 9, should the subject limited to a medical device (such as audio signal production device or application service provider device or so), then above reason for refusal may be resolved. For example, claim 1 may be amended as “A method of providing a stimulus to the auditory system of an individual experiencing tinnitus or hyperacusis by an audio signal producing device, wherein said method comprises...”

< Claims with No Reasons for Refusal >

No reasons for refusal have found in the invention according to claims 11 to 24, at this moment. Should any reasons be found, the reasons for refusal will be notified.

Patented Claim 1 (Methods)

【Claim 1】

A method for producing an audio signal that provides a stimulus to the auditory system of an individual experiencing tinnitus or hyperacusis by an audio signal producing device, the method comprising;

providing an audio signal including peaks and troughs;

producing a predetermined masking algorithm designed to modify the intensity of said audio signal at selected frequencies for providing intermittent masking of tinnitus based on a basic audiometric measurement information of the individual and to achieve a required equalization response for providing a comparative equal sensation level at every frequency; and

spectrally modifying the audio signal in accordance with the predetermined masking algorithm wherein, in use at a comfortable listening level, when the spectrally modified audio signal is heard by the individual during the peaks, the tinnitus is substantially completely obscured and the individual perceives significant masking of the tinnitus, and during the troughs, the individual may occasionally perceive the tinnitus.

Comments

- This application was granted by amending “a rehabilitation method” to “an audio signal producing method”, and by emphasizing that these methods are not “a method for curing ” or “a method for diagnosing”.
- “A Law of Nature” in itself cannot be subject to patents, however, utilization of that law can be subject to patents. In this case, the following signal transformation was recognized to be granted. The signal transformation designed that “the tinnitus is substantially obscured when the audio signal is at the peaks and the tinnitus is perceived when the audio signal is at the troughs” was admitted as an utilization of the Law of Nature.
- Amendment was required so as to make clear that the method is conducted by device in itself, since the method conducted mainly by human being cannot be patented.
- This case is similar to the Bilski case of the United States.
(CAFC full court decision on October 30, 2008, supreme court decision of machine-or-transformation test on June 28, 2010)



Rejected Claims by Assessing Inventive Step (Medium)

【Claim 13】

A tinnitus rehabilitation sound recording medium for providing relief to a person suffering from the disturbing effects of tinnitus, the sound recording medium comprising:

an audio signal spectrally modified in accordance with a predetermined masking algorithm designed to modify the intensity of the audio signal at selected frequencies,

whereby, in use, when the sound recording is heard by the person it provides significant masking of the tinnitus.

Patented Claim (Medium)

A sound recording medium for providing a stimulus to the auditory system of an individual experiencing tinnitus or hyperacusis, the sound recording medium comprising an audio signal including peaks and troughs; wherein

the audio signal is spectrally modified in accordance with the predetermined masking algorithm designed to modify the intensity of said audio signal at selected frequencies for providing intermittent masking of tinnitus based on a basic audiometric measurement information of the individual and to achieve a required equalization response for providing a comparative equal sensation level at every frequency; and

the audio signal is spectrally modified, in use at a comfortable listening level, when the spectrally modified audio signal is heard by the individual during the peaks, the tinnitus is substantially completely obscured and the individual perceives significant masking of the tinnitus, and during the troughs, the individual may occasionally perceive the tinnitus.

Comments

- Audio signal corresponding to the patented method for producing audio signal can be granted as a recording medium.
- We did a search regarding whether an audio signal itself is registered or not through the data base of Japanese Patent Office, however, there were no examples of registration.
- It is possible to register in the program expression format.

Rejected Claim due to the Methods for Diagnosing and Curing (Method)

【Claim 15】

A method of using a computer to provide access to a predetermined masking algorithm used in tinnitus rehabilitation for providing relief to a person suffering from the disturbing effects of tinnitus, the method comprising:

- receiving on-line, from a user, data representing an audiogram of the person suffering from tinnitus;

- processing said audiogram data using said predetermined masking algorithm to produce required equalisation response data based on said audiogram data; and,

- transmitting said required equalisation response data to the user.

Patented Claims by Changing the Method to the Device (Newly Added Claims of Apparatus)

【Claim 13】

- An application service provider apparatus for providing data for the production of audio signal used to provide a stimulus to the auditory system of an individual experiencing tinnitus or hyperacusis, characterized by comprising;
 - means of receiving a data showing a audiogram of said individual that transmits through a website from a personal computer,
 - means of producing a required equalization response data designed to modify the intensity of said audio signal at selected frequencies for providing intermittent masking of tinnitus based on the said received data showing the audiogram of said individual, by using a predetermined masking algorithm achieving the required equalization response for providing a comparative equal sensation level at every frequency, and
 - means of transmitting said produced required equalization response data to said personal computer.



Comments

- It might be able to establish proprietary rights by amending the expression form of invention from methods for internet-based curing and diagnosing to data transmitting apparatus.

Information Regarding Applications

- Japanese Application No. 2000-605446 (March 17, 2000)
- International Application PCT/AU2000/000207
- International Publication No: ([WO2000/056120](#))
- International Publication Date(September 21, 2000)
- Translation Filing Date(September 17, 2001)
- Japanese Publication No. ([2002-538912](#))
- Japanese Publication Date(November 19, 2002)
- Patent Granted (January 9, 2009)

Current Status of Corresponding EP Application

- Reply to a communication from the examining division
30.11.2009 Despatch of communication that the application is refused, reason: substantive examination Appeal following examination 22.01.2010 Appeal received No. T0807/10
03.03.2010 Statement of grounds filed
- Divisional application(s)
P20050008577 / [EP1559370](#)

US Patent (Tinnitus Rehabilitation Method)

- 1. A tinnitus rehabilitation method for providing relief to a person suffering from the disturbing effects of tinnitus, the method comprising:
- providing an audio signal including peaks and troughs; producing a predetermined masking algorithm designed to modify at least one of peaks and troughs of at least a portion of the audio signal at selected frequencies for providing intermittent masking of tinnitus and to account for a basic audiometric configuration of the person; and
- spectrally modifying the audio signal in accordance with the predetermined masking algorithm wherein, in use at a comfortable listening level, when the spectrally modified audio signal is heard by the person during the peaks, the tinnitus is substantially completely obscured and the person perceives significant masking of the tinnitus, and during the troughs, the person may occasionally perceive the tinnitus.

US Patent (Recording Medium)

- 11. A tinnitus rehabilitation sound recording (medium) for providing relief to a person suffering from the disturbing effects of tinnitus, the sound recording (medium) comprising:
- an audio signal which is reproducible on a playback device to provide the signal to the person, said audio signal including peaks and troughs, spectrally modified in accordance with a predetermined masking algorithm, for intermittent masking of tinnitus, designed to modify at least one of the peaks and the troughs of at least a portion of the audio signal at selected frequencies,
- and wherein said predetermined masking algorithm is specifically produced to account for the basic audiometric configuration of the person whereby, in use at a comfortable listening level, when the sound recording is heard by the person during the peaks, the tinnitus is substantially completely obscured and the person perceives significant masking of the tinnitus, and during the troughs, the person may occasionally perceive the tinnitus.

US Patent (Invention for Internet Use)

- 13. A method of using a computer to provide access to a predetermined masking algorithm used in tinnitus rehabilitation for providing relief to a person suffering from the disturbing effects of tinnitus, the method comprising:
 - receiving on-line, from a user, data representing an audiogram of the person suffering from tinnitus;
 - processing said audiogram data using said predetermined masking algorithm to produce required equalisation response data based on said audiogram data; and,
 - transmitting said required equalisation response data to the user for use in the predetermined masking algorithm to provide relief from the tinnitus.

US Patent (Invention of Devices)

- 15. A tinnitus rehabilitation device for providing relief to a person suffering from the disturbing effects of tinnitus, the device comprising:
- a signal filter configured to spectrally modify at least a portion of an audio signal including peaks and troughs in accordance with a predetermined masking algorithm designed to modify at least one of the peaks and the troughs of at least a portion of the audio signal at selected frequencies,
- and wherein said predetermined masking algorithm accounts for the basic audiometric configuration of the person whereby, in use at a comfortable listening level, when the spectrally modified audio signal is heard by the person during the peaks, the tinnitus is substantially completely obscured and the person perceives significant masking of the tinnitus, and during troughs, the person may occasionally perceive the tinnitus.

Existing Situation of Patent Protection for Medical Field in Japan, Europe and the United States.

(Abstracted from “*Summarization regarding the Situation of Patent Protection for Medical related Procedure*” issued by Intellectual Property Strategy Headquarters in 2004)

Medical Device

	Methods				Products
	Techniques provided by the Physician	Operation Method of Medical Device	Internal Control Methods of Medical Device	Production Methods of Medical Device	Mechanism, Function and Control Means of Medical Device
Japan	No	Yes	Yes	Yes	
United States	Yes		Yes	Yes	Yes
Europe	No (Operating• Curing)	Yes/No? (Diagnosing)	Yes	Yes	



Japanese Criteria for Examination

- An operation method of medical device does not apply to “a method for operating, curing and diagnosing human” and is patentable, since it expresses the function provided to the medical device itself.
- However, the process made by the physician and the methods including instrumental function process for human body do not apply to the operation method of medical device, and is not patentable.