

Note: When any ambiguity of interpretation is found in this provisional translation, the Japanese text shall prevail.

Part II: REQUIREMENTS FOR PATENTABILITY

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Chapter 1 Industrially Applicable Inventions

The first paragraph of Article 29(1) of the Patent Act reads:

“Any person who has made an invention which is industrially applicable may obtain a patent therefor ...”

It has been long established in theory and practice to consider that the above provision requires an invention to be “statutory” as well as “industrially applicable.” These Guidelines, in accordance with this established rule, explain these two requirements, i.e., being “statutory” and “industrially applicable.”

1. Statutory Inventions

Article 2(1) of the Patent Act defines a statutory invention as a highly advanced creation of technical ideas utilizing a law of nature. It should be noted, however, that the term “highly” has been introduced in the definition to differentiate “invention” from “device” under the Utility Model Act, and this term is disregarded in judging whether an invention is statutory or not.

The following is a list of non-statutory inventions.

1.1 List of Non-statutory Inventions

Since it is not a “creation of a technical idea utilizing a law of nature,” any one of the following is not considered to be a statutory invention.

(1) A law of nature as such

Since statutory inventions shall utilize a law of nature, a law of nature as such, like a law of preservation of energy or a law of universal gravitation, is not considered as a statutory invention.

(2) Mere discoveries and not creations

One of the requirements for a statutory invention is to be a “creation”, and thus, mere discoveries, such as discoveries of natural things like an ore or natural phenomena, for which an inventor does not consciously create any technical idea, are not considered to be a statutory invention.

However, if things in nature such as chemical substances or microorganisms have been isolated artificially from their surroundings, then those are creations and considered to be a statutory invention.

(3) Those contrary to a law of nature

If a matter necessary to define an invention involves any means contrary to a law of nature, the claimed invention is not considered to be a statutory invention (See: Example 1). The so-called perpetual motion is an example contrary to the second law of thermodynamics.

(4) Those in which a law of nature is not utilized

If claimed inventions are any laws as such other than a law of nature (e.g. economic laws), arbitrary arrangements (e.g. a rule for playing a game as such), mathematical methods or mental activities, or utilize only these laws (e.g. methods for doing business as such), these inventions are not considered to be statutory because they do not utilize a law of nature (see Examples 2-4).

Example 1: Computer programming languages

Example 2: A method of collecting money for an electricity bill or a gas bill etc., by rounding off the total amount to be collected to the nearest 10 yen unit.

Even if a part of matters defining an invention stated in a claim utilizes a law of nature, when it is judged that the claimed invention considered as a whole does not utilize a law of nature, the claimed invention is deemed as not utilizing a law of nature.

Example 3: A method of plying a container vessel to transport a large amount of fresh water from a region where crude oil is expensive and fresh water is inexpensive to another region where crude oil is inexpensive and fresh water is expensive, and after unloading the fresh water, transporting a large amount of crude oil instead of the water to the homeward voyage.

Example 4: A method of billboard advertising using utility poles, characterized by forming in advance groups A, B, C, D, ... with a prescribed number of poles in each group, placing a holding frame to post thereon a billboard for each pole, and posting the billboards in each group on holding frames placed to poles in each group in circulation in a certain time interval (See: Tokyo High Court Judgment Sho 31.12.25 (Syowa 31 (Gyo Na) 12))

On the contrary, even if a part of matters defining an invention stated in a claim does not utilize a law of nature, when it is judged that the claimed invention as a whole utilizes a law of nature, the claimed invention is deemed as utilizing a law of nature.

As stated above, the characteristic of the technology is to be taken into account in judging whether a claimed invention as a whole utilizes a law of nature.

Notes:

For inventions relating to a method for doing business or playing a game, since there are cases in which the claimed invention a part of which utilizes an article, apparatus, device, system, etc., is judged as not utilizing a law of nature when considered as a whole, careful examination shall be required. (See: Examples 5-7)

There is possibility for an invention to be qualified as statutory where the invention is made not from a viewpoint of a method of doing

business or playing a game but from a viewpoint of computer software-related inventions such as software used in doing business or in playing a game. (See: "Part VII: Chapter 1. Computer Software-Related Inventions, 2.2")

(5) Those not regarded as technical ideas

(a) Personal skill (which is acquired through personal experience and cannot be shared with others as a knowledge due to lack of objectivity)

Example: A method of throwing a split-fingered fast ball characterized in the way of holding the ball in fingers and throwing the same

(b) Mere presentation of information (where the feature resides solely in the content of the information, and the main object is to present information)

[Examples]

written manual for instructing an operation of a machine or directing a use of a chemical substance, audio compact disc (where the feature resides solely in music recorded thereon), image data taken with a digital camera, program of an athletic meeting made by a word processor, or computer program listings (mere representation of program codes by means of printing them on paper, displaying them on a screen, etc.)

However, if technical features reside in presentation of information (presentation per se, a means for presentation, a method for presentation, etc.), claimed inventions are not considered as mere presentation of information.

Example 1: A test pattern for use in checking the performance of a television set (where a technical feature resides in the pattern per se)

Example 2: A plastic card on which information is recorded with characters, letters and figures embossed on it (enabling one to copy the information by affixing the card on a paper, in this sense the technical feature residing in the means for presentation)

(c) Aesthetic creations

Example: paintings, carvings, etc.

(6) Those for which it is clearly impossible to solve the problem to be solved by any means presented in a claim

Example: A method for preventing explosion in a volcano by forming balls of neutron-absorbing material (e.g., boron) covered with substance having high melting temperature (e.g., tungsten) and throwing them into the volcanic vent (This invention allegedly works on the assumption that

volcanic explosion is caused by nuclear fission of substances like uranium at the bottom of the volcanic vent.)

2. Industrial Applicability

Here, the word "industry" is interpreted in a broad sense, including mining, agriculture, fishery, transportation, telecommunications, etc., as well as manufacturing.

The following is a list of industrially inapplicable inventions. In principle, an invention which does not correspond to any one of the followings is considered as industrially applicable.

2.1 List of Industrially Inapplicable Inventions

2.1.1 Methods of surgery, therapy or diagnosis of humans

Methods of surgery, therapy or diagnosis of humans have been termed "medical activity" and are normally practiced by medical doctors (including those who are directed by medical doctors, hereinafter referred to as "medical doctors").

Methods for contraception or delivery are included in "methods of surgery, therapy or diagnosis of humans."

Even if methods of surgery, therapy or diagnosis are practiced on animal bodies in general, unless it is clear that the methods practiced on a human body are explicitly excluded, the methods are deemed as being "methods of surgery, therapy or diagnosis of humans."

2.1.1.1 Types of methods considered to be classified as "methods of surgery, therapy or diagnosis of humans"

(1) Methods of surgery of humans (Refer to Examples 8-1, 9-1, 10-1, 11-1, 12-1)

Methods of surgery of humans include the followings:

(a) Methods for surgical treatment (such as incision, excision, centesis, injection and implant)

(b) Methods of using (e.g., inserting, moving, maintaining, operating and extracting) a medical device (e.g., a catheter and an endoscope) inside the human body (excluding inside the mouth, inside the external nostril, and inside the external ear canal)

(c) Preparatory treatment for surgery (e.g., anesthetic treatment for surgery and method of disinfecting skin before injection)

Cosmetic methods having surgical operations whose purpose is not therapeutic or diagnostic are also considered as "methods of surgery of humans."

(2) Methods of therapy of humans (Refer to Examples 13-1, 14-1, 15-1, 16-1, 17-1, 18-1, 22-1)

Methods of therapy of humans include the followings:

- (a) Methods of administrating medicine or giving physical treatment to a patient for curing or restraining a disease
- (b) Methods of implanting substitute organs such as artificial internal organs or artificial limbs
- (c) Methods of preventing a disease (e.g., methods of preventing tooth decay or influenza)

Methods of treatment for the maintenance of physical health (e.g., methods of massage or *shiatsu* therapy) are also considered to be methods of preventing a disease.

- (d) Preparatory treatment for therapy (e.g., method for arranging electrodes for the electrical therapy), supplemental methods for improving treatment effects (e.g., rehabilitation methods), or methods for nursing associated with the treatment (e.g., methods to prevent bedsores)

(3) Methods of diagnosis of humans

“Methods of diagnosis of humans” include methods of judging for the medical purpose the physical condition of a human body such as diseases and physical health, the mental condition of a human body, or prescription or treatment/surgery plans based on these conditions.

Case 1: Methods of judging whether the patient has had a stroke by observing the image obtained by the MRI scan.

2.1.1.2 Types of methods not considered to be classified as “methods of surgery, therapy or diagnosis of humans”

(1) A medical device or a medicinal substance is a product, and is not considered as “methods of surgery, therapy or diagnosis of humans.” It should be noted that the combination of two or more products is not considered as “methods of surgery, therapy or diagnosis of humans.” (Examples 13-2, 14-2, 15-2)

(2) A method for controlling the operation of a medical device is not considered to be classified as “methods of surgery, therapy or diagnosis of humans” as long as the function of the medical device is represented as a method. The method for controlling the operation of the medical device here may include not only a method for controlling the internal operation of the medical device but also a functional and/or systematic operation provided to the medical device, such as the moving, opening and/or closing of an incising means in accordance with an operating signal, the emitting and/or receiving of a radioactive ray, an electromagnetic wave, a sound wave, or the like. (Examples 8-2, 9-2, 10-2, 11-2, 12-2, 16-2 to 16-4, 17-2, 18-2, 19-2, 20-2, 24-2, 25-3)

However, a method including a step, as a matter to define claimed invention, with an action of a medical doctor (for example, a step where

a medical doctor operates a device in order to provide medical treatment in accordance with a symptom) and/or a step with an influence on the human body by a device (for example, the incision and/or excision of a specific part of a patient by a device or the irradiation of radiation, electromagnetic wave or sound wave by a device) is not considered to be a method for controlling the operation of the medical device.

(3) The following methods for gathering various kinds of information by, e.g., measuring structures and functions of the various organs of the human body, is not considered to be methods of diagnosis of humans unless it includes the steps of judging for the medical purposes the physical condition of a human body such as diseases and physical health, the mental condition of a human body, or prescription or treatment/surgery plans based on these conditions. (Example 19-1, 20-1, 21)

(a) Methods of extracting samples and data from the human body, or methods of analysing, e.g., comparing such samples and data with standards.

Case 1: A method for an influenza test by extracting oral mucous membranes with cotton bud

Case 2: A method for capturing the image of the lung by X-ray irradiation to the chest

Case 3: A method for measuring the body temperature by inserting an electronic ear thermometer into external ear canal

Case 4: A method for judging the sugar level in the urine by dipping the test strip in the collected urine sample, and comparing the color of the test strip with the colors on the color chart

Case 5: A method of examining the susceptibility of the examinee to hypertension by determining the type of base on the nth line of the base sequence of the X gene of the examinee and comparing the base with a standard in which when the base type is A the susceptibility is low, and when the type is G the susceptibility is high

(b) Preparatory treatment for measuring structures or functions of various organs of the human body

Case 6: A method of preventing the uneven smear of the jelly for the ultrasonography that is spread on the body

However methods that include steps corresponding to methods of surgery or therapy of humans are deemed to be “methods of surgery or therapy of humans.” (Examples 9-1, 10-1, 11-1, 18-1)

2.1.1.3 Methods for treating samples that have been extracted from the human body

Methods for treating samples that have been extracted from the human

body (e.g., blood, urine, skin, hair, cells or tissue) and methods for gathering data by analyzing such samples are not considered to be "methods of surgery, therapy or diagnosis of humans." (Example 25-2)

However, if a method for treating these samples or analyzing the samples in the process is performed on the presumption that the samples are to be returned to the same body (e.g., a method of dialyzing blood), then, such a method is qualified to be placed under the category of "methods of surgery, therapy or diagnosis of humans." (Example 24-1, 25-1)

Even if a method for treating these samples is performed on the presumption that the samples are to be returned to the same body, the following are not considered to be "methods of surgery, therapy or diagnosis of humans." (Example 22-2, 23-1, 23-2, 23-3)

(1) A method for manufacturing a medicinal product (e.g., blood preparation, vaccine, genetically modified preparation and cell medicine) by utilizing raw material collected from a human body

(2) A method for manufacturing a medical material (e.g., an artificial substitute or alternative for a part of the human body, such as an artificial bone, a cultured skin sheet, etc.) by utilizing raw material collected from a human body

(3) A method of manufacturing an intermediate product for a medicinal product or a medical material (e.g. methods for differentiation and induction of the cells, methods for separation and purification of the cells) by utilizing raw material collected from a human body

(4) A method of analyzing a medicinal product or a medical material, or intermediate product thereof which is manufactured by utilizing raw material collected from a human body

2.1.2 Commercially inapplicable inventions

An invention concerning marketable or tradable subject matter is considered commercially applicable. On the other hand, inventions indicated in (i) and (ii) below are regarded as commercially inapplicable, and hence industrially inapplicable.

(i) an invention applied only for personal use, such as a method of smoking

(ii) an invention applied only for academic or experimental purposes

It should be noted that such an invention as a "method of waving hair", which is used in the beautician field while being personally applied, is not considered as an "invention applied only for personal use." Likewise, a "kit for scientific experiments," which is used in experiments at school, is not considered as an "invention applicable only for academic or experimental purposes" as it is marketable and tradable.

2.1.3 Practically inapplicable inventions

An invention which can not be practically implemented is not considered

as an "industrially applicable invention" even if it works in theory.

Example: A method for preventing an increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole earth's surface with an ultraviolet ray-absorbing plastic film

3. Notes for examining the requirement for Industrial Applicability

The burden of proof regarding the requirement for industrial applicability is placed on the applicant. However, upon noticing that a claimed invention does not comply with the requirements for industrial inapplicability, the ground should be indicated as specifically as possible in the notification of reasons for refusal.

4. Examples

These examples were put together to explain the requirement of “Industrially Applicable Inventions” in the first paragraph of Article 29(1) of the Patent Act. Therefore, it is to be noted that some of the scope of claims in the examples have been modified, e.g., simplified in parts to provide an explanation easier to understand. Additionally, it does not mean the examples do not have reasons for refusal such as lack of novelty/inventive steps or description requirements of the description and the claims.

The list of examples is shown below.

4.1 Statutory invention requirement

4.1.1 Methods contrary to a law of nature

Example 1 A method of plating copper with iron (contrary to a law of nature)

4.1.2 Methods not utilizing a law of nature

Example 2 A method for calculating the sum of natural numbers n to $n+k$ (not utilizing a law of nature)

Example 3 A method of teaching in science and mathematics courses (not utilizing a law of nature)

Example 4 A method for drawing a regular N -polygon inscribed in a given circle (not utilizing a law of nature)

Example 5 A method of playing a game (not utilizing a law of nature)

Example 6 A method for determining a selling price of a commodity (not utilizing a law of nature)

Example 7 A method for holding a party (not utilizing a law of nature)

4.2 The requirement of industrial applicability

4.2.1 Methods of surgery of humans

Example 8-1 A method for treating an affected part by micro operation robot (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 8-2 A method for controlling the operation of a micro operation robot system (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 9-1 A method for sampling body fluid (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 9-2 A method for controlling the operation of a body fluid sampling device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 10-1 A method for the observation of the celom by using an endoscope (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 10-2 A method for controlling the operation of an endoscope (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 11-1 A method for contrast magnetic resonance imaging (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 11-2 A method for controlling a magnetic resonance imaging device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 12-1 A method for displaying superimposed images of an object being cut and a cutting apparatus (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 12-2 A method for controlling a device for displaying superimposed images of an object being cut and a cutting apparatus (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

4.2.2 Methods of therapy of humans

Example 13-1 A method for the treatment of cancer (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 13-2 A system for cancer treatment (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 14-1 A method for regenerating cartilage (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 14-2 An implant material for cartilage regeneration (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 15-1 A method for the treatment of cardiac infarction (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 15-2 A composition for treatment of cardiac infarction (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 16-1 A method for giving electrical stimulus by a pacemaker (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 16-2 A method for controlling a pacemaker (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 16-3 A method for controlling a pacemaker (An invention not considered

as “methods of surgery, therapy or diagnosis of humans”)

Examples 16-4 A method for controlling the operation of a pacemaker (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 17-1 A method for retinal stimulation using an artificial eye system (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 17-2 A method for controlling an artificial eye system (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 18-1 A method for X-ray irradiation (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 18-2 A method for controlling the operation of an X-ray device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

4.2.3 Methods for gathering data

Examples 19-1 A method for X-ray CT scanning (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 19-2 A method for controlling an X-ray CT scanner (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 20-1 A method for magnetic resonance imaging (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 20-2 A method for controlling the operation of magnetic resonance imaging device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 21 A method for nuclear medicine imaging (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

4.2.4 Methods for treating samples that have been extracted from the human body

Examples 22-1 A method for Gene therapy (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 22-2 A method for manufacturing cells for gene therapy (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 23-1 A method of inducing differentiation of cells (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 23-2 A method of separating and purifying differentiation-induced cells (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 23-3 A method of analyzing a ratio of separated and purified cells (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 24-1 A method for blood purification (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 24-2 A method for controlling the operation of a blood purifying device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 25-1 A method for measuring hematocrit values of blood (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Example 25-2 A method for measuring hematocrit values of extracted blood (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Example 25-3 A method for controlling a blood hematocrit measuring device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

4.2.5 Methods relating to assisting devices

Examples 26-1 A method for judging a motion state of walking (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 26-2 A method for controlling a power assisting device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Examples 26-3 A method for power assisting (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

4.1 Statutory invention requirement

4.1.1 Methods contrary to a law of nature

Example 1 A method of plating copper with iron (contrary to a law of nature)

Claim

A method of plating copper with iron, comprising the steps of immersing a piece of copper piece in an aqueous solution containing iron ions, thereby forming an iron layer on said piece of copper.

Outline of Detailed Explanation of the Invention

Electroplating has been a conventional method for plating copper with iron. The present invention provides a method which enables plating of a piece of copper with hard iron layer by only immersing the copper piece in an aqueous solution containing iron ions such as iron sulfate, using simpler equipment than that conventionally employed.

[Explanation]

It is common general technical knowledge that iron has a higher tendency to ionize than copper. Therefore it is impossible to form a hard iron layer over a piece of copper by only immersing it in an aqueous solution containing iron ions such as iron sulfate.

This implies that the claimed invention involves a means to solve the problem which is contrary to a law of nature. Therefore, it is impossible to solve the stated object and the claimed invention is non-statutory.

4.1.2 Methods not utilizing a law of nature

Example 2 A method for calculating the sum of natural numbers n to $n+k$ (not utilizing a law of nature)

Claim

A method for calculating the sum of natural numbers n to $n+k$ in accordance with the formula:

$$s = (k+1)(2n+k)/2.$$

Outline of Detailed Explanation of the Invention

The sum of natural numbers n to $n+k$, noted as "s," is expressed by:

$$s = n+(n+1)+(n+2)+ \dots +(n+k) \quad \dots(1)$$

The equation remains unchanged even if the order of addition changes. Thus, the sum is expressed in a different way as follows by reversing the sequence of the right side of the equation:

$$s = (n+k)+(n+k-1)+(n+k-2)+ \dots +(n+1)+n \quad \dots(2)$$

The combination of equations (1) and (2) results in

$$2s = (2n+k)+(2n+k)+(2n+k)+ \dots +(2n+k)$$

The right side of the equation consists of $(k+1)$ times $(2n+k)$, and it follows that the sum is simply calculated by

$$s = (k+1)(2n+k)/2$$

[Explanation]

A method of calculation is a mathematical process for processing given numbers or equations representing certain relations in mathematics or other fields of science in accordance with mathematical algorithm.

A mere mathematical process based on the formula:

$$s = (k+1)(2n+k)/2$$

is carried out in the claimed invention, and the invention utilizes solely laws other than a law of nature. The claimed invention is therefore non-statutory.

Example 3 A method of teaching in science and mathematics courses (not utilizing a law of nature)

Claim

A method of teaching in science and mathematics courses of lower elementary school grades, characterized in that the time ratio for introduction, development, and summary respectively 3:2:1.

Outline of Detailed Explanation of the Invention

Conventionally, education of lower grade children has been carried out in the order of introduction, development and summary, at the ratio of 1:4:1 respective time allocation ratio. The present invention is to improve the teaching of science and mathematics by changing the ratio into 3:2:1, taking account of the reasoning and memorizing ability of children.

[Explanation]

Since the “teaching” means providing instruction, it is a kind of mental activity.

This invention, considering the reasoning and memorizing ability of children, employs the time ratio of 3:2:1 for introduction, development and summary in lower elementary school grades in order to improve the teaching of science and mathematics courses.

It follows that the claimed invention utilizes solely laws other than a law of nature and is therefore non-statutory.

Example 4 A method for drawing a regular N-polygon inscribed in a given circle (not utilizing a law of nature)

Claim

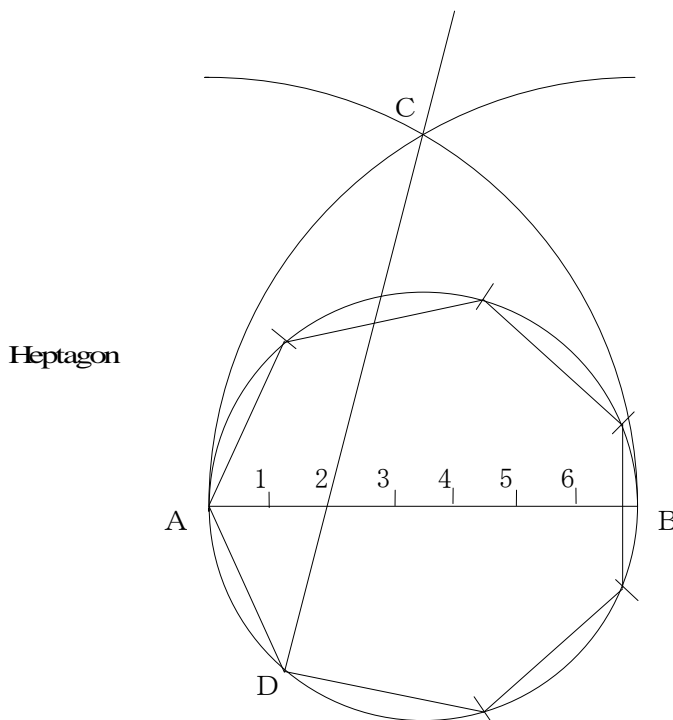
A method for drawing a regular N-polygon inscribed in a circle comprising the steps of:

- setting the diameter AB of a given circle as the radius;
- drawing circles having said radius with A and B as centers;
- denoting one of the intersecting points thereof as C;
- denoting as D the intersecting point of the given circle and the linear line connecting the second point from the A of the N equipartition points of the diameter;
- equipartitioning by a length equal to AD the circumference of the circle; and
- connecting equipartitioned points on the circumference successively with linear lines to construct a regular N polygon.

Outline of Detailed Explanation of the Invention

This method makes possible the easy drawing of a regular N polygon in a given circle.

(Drawing)



[Explanation]

Generally, the term "drawing" is used with the meaning of depicting a figure which satisfies given conditions in geometry. In order to depict a figure satisfying such given conditions, it is a prerequisite to assume that several basic

constructions (known as postulates) and several axioms are true. A set of the determined postulates and axioms make possible certain constructions, and a change in the postulates and axioms inevitably leads to a change in the constructions. Therefore, pure geometric construction is nothing but an operation based on assumed postulates and axioms, and utilizes laws other than laws of nature.

The application of the above considerations to this example follows that the claimed invention is nothing more than a pure geometric construction and utilizes solely laws other than laws of nature. The claimed invention is therefore non-statutory.

Example 5 A method of playing a game (not utilizing a law of nature)

Claim

A method of playing a game, comprising the steps of:
piling up from larger to smaller several pieces having similar shape but different sizes at one of the given three positions; and
moving the pieces on top one by one to other positions without placing a large piece on a small piece, thereby moving all the pieces to another position in the least number of moves.

Outline of Detailed Explanation of the Invention

The present invention enables players to enjoy an interesting, intellectually challenging game regardless of the number of players.

[Explanation]

A game is generally performed following artificial rules unrelated to a law of nature, relying on human mental abilities such as reasoning, memorization, skill, luck, inspiration and chance.

Rules employed in the claimed invention, such as the moving of pieces and prohibited actions, are artificial arrangements to perform the game among players, and a law of nature is not utilized here. The claimed invention is therefore non-statutory.

Example 6 A method for determining a selling price of a commodity (not utilizing a law of nature)

Claim

A method for determining the selling price of a commodity comprising the steps of:

attaching a label on a product to indicate the production time of the product, an expiration date and a list price at the production time, and

determining a selling price at a selling time based on the formula:

$$\text{Selling price} = f(\text{selling time}) \times \text{list price}$$

wherein the function 'f' is a monotonous decreasing function satisfying the condition:

$$0 \leq f \leq 1$$

Outline of Detailed Explanation of the Invention

In the past, products of the same kind were placed on the same shelf for selling even if their production times differed. Therefore, those customers who prefer the freshness of a product tend to check the production time and select the most recent one, and therefore old products usually remain. As a result, those products that passed the expiration date lost the commercial value, and the cost to discard them as garbage was generated and this resulted in a loss of profit for the shop owner.

Then, in order to increase probability of selling old products, the shop owner tried to relocate products in a certain time interval in such a manner that old ones are placed at the front side of a shelf and new ones at the rear side. However, as shop floor space becomes larger, the cost for rearranging products in a certain time interval increases, and it always involved a risk that customers had a bad impression when they saw the rearrangement work.

Therefore, the problem to be solved by this invention is to provide a method for determination of the selling price of a commodity in that a lower selling price of the product can be set depending on the length of lapsed selling time by calculating the selling price using the formula:

$$\text{Selling price} = f(\text{selling time}) \times \text{list price}$$

wherein the function 'f' is a monotonous decreasing function satisfying the condition:

$$0 \leq f \leq 1$$

in order to reduce the number of products whose selling period has expired as few as possible and to save the costs for rearrangement of the products on the shelf and for discarding the old products remained as garbage, without giving a bad impression created by the rearrangement to the customers. By this invention, the number of old products which remain otherwise can be reduced even without relocating the products on the shelf, as it is expected that customers who prefer the freshness will buy relatively expensive new products while those customers who prefer thrift will buy relatively economical old products. Furthermore, because

the selling price of the products whose selling period has expired becomes zero and those customers who are conscious of thrift may take out some of the products for free, so that a part of the cost for discarding the old products remained can be reduced.

Now, the function 'f' can be set based on the following formula:

$$f(\text{selling time}) = \log_{10} \left(1 + 9 \max \left(\frac{\text{expiration date} - \text{selling time}}{\text{expiration date} - \text{production time}}, 0 \right) \right)$$

[Explanation]

A method for determining the selling price of a commodity defined in the claim is matter using a label as an article, but since it relies on economic laws or artificial arrangements, the claimed invention, considered as a whole, is not utilizing a law of nature.

The claimed invention is therefore non-statutory.

[Reference]

When the statement of this claim is amended as follows:

"A method for determining the selling price of a commodity in a cash register equipped with reading means for reading two dimensional bar codes indicating the production time, the expiration date and the list price of the product recorded on a label attached on the product, clocking means for outputting the current time, arithmetic means for calculating the selling price, display means for indicating the selling price, control means for controlling said reading means, clocking means, an arithmetic means, and display means, the method comprising the steps of:

reading by said reading means, the two dimensional bar codes recorded on a label attached to the product;

receiving by said control means, the information of the two dimensional bar codes outputted from said reading means;

outputting by said control means, said received bar codes information and the current time obtained by said clocking means to the arithmetic means;

calculating by said arithmetic means, the selling price of the product based on the formula:

$$\text{Selling price} = f(\text{selling time}) \times \text{list price}$$

wherein, the function 'f' is a monotonous decreasing function satisfying the condition:

$$0 \leq f \leq 1$$

outputting the calculation result to said control means; and indicating by said control means, the calculation result on said display means",

the amended claimed invention is deemed as the "creation of technological ideas utilizing a law of nature." (For practical judgment, see "Part VII: Chapter 1. Computer Software-Related Inventions")

Example 7 A method for holding a party (not utilizing a law of nature)

Claim

A method for holding a party, comprising the steps of:
sending e-mail to invite to the party with message stating that those who respond early will receive a gift at the party, to the members based on the invitation list;
receiving e-mail to respond to said e-mail confirming the attendance;
registering the order of arrival of which said email for response is received in the name list of expected participants;
collecting the party fee at the party reception desk; and
giving a gift in the order of arrival registered in said name list after collecting said party fee.

Outline of Detailed Explanation of the Invention

After calling for participation to the party, it is meaningless for the party planner if the actual number of participants is far less than expected. Then, just to be sure, the expected attendance will be confirmed in advance by e-mail for instance instead of return postcards, but this does not assure responses before the due date. Even if responses are received, it is uncertain if the members actually come to the party.

According to this invention, by telling members that those who responded early will receive a good gift, the probability of participation will increase and quick responses can be expected. Therefore, by grasping the anticipated attendance early, loss of expenses for preparation of the party such as meals can be reduced.

The cost of the gifts may be appropriated by the reduced expenses, previously including in the party fee, or by donation from the sponsors on the condition that the sponsors' goods will be used in the party.

[Explanation]

A method for holding a party defined in the claim uses a system of e-mailing for the confirmation of attendance, but dependent on artificial arrangement to make the confirmation between the party planner and the participants and to give gifts in the entry order, and the claimed invention, considered as a whole, is deemed as not utilizing a law of nature.

The claimed invention is therefore non-statutory.

[Reference]

When the statement of this claim is amended as follows:

"An operation method of an information processing system for supporting party holding, comprising the steps of:

an input means;

an e-mail transmission and receiving means;

a storage means of anticipated participants list to memorize names, e-mail addresses, and the order of response e-mail confirming the attendance from the anticipated participants;

a storage means for memorizing a message telling that a gift will be given

to the participants in the order of receiving the response e-mail;
a display means; and
a control means;

wherein, said control means comprising the steps of:

reading e-mail addresses from said storage means of the anticipated participants list and the message stored in said message storage means;

transmitting said message as an invitation e-mail requesting attendance confirmation to said e-mail addresses by the e-mail transmission and receiving means;

detecting response e-mails received by said e-mail transmission and receiving means;

memorizing a response e-mail received every time it is detected into said storage means of anticipated participants list in the order the response e-mails received; and

outputting all the names of anticipated participants of those who responded stored in said storage means of the anticipated participants list and the order of received response e-mail, when the instruction of the end of detection of response e-mails is sensed by said input means",

the amended claimed invention is deemed as the "creation of technical idea using a law of nature" (For practical judgment, see "Part VII: Chapter 1. Computer Software-Related Inventions")

4.2 The requirement of industrial applicability

4.2.1 Methods of surgery of humans

Example 8-1 A method for treating an affected part by micro operation robot (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for treating an affected part by using a micro operation robot having at its head optical observing means and incising means and having at its bottom receiving means for receiving manipulator signals from an extracorporeal remote operation device, comprising the steps of; operating a manipulator in order to give medical treatment to the affected part while viewing the monitor of the remote operation device, receiving a manipulator signal from the remote operation device by the receiving means, and incising the affected part of a patient by an incising means based on the signal received.

Outline of Detailed Explanation of the Invention

The capsule type micro operation robot of the present invention can, owing to very delicate constitution thereof, perform treatment such as incision, excision, or the like of the affected part by remote control in an organ such as a blood vessel or the like, without excessively burdening the patient.

[Explanation]

The matter reading “operating a manipulator in order to give medical treatment to the affected part while viewing a monitor of the remote operation device” includes the step with an action of a medical doctor to view a monitor and to operate a manipulator for treating the affected part. Furthermore, the matter reading “incising the affected part of a patient by incising means” depicts the step with an influence on the human body by the device.

Accordingly, the claimed method is not considered to be a method for controlling the operation of the medical device.

As a result, the method in this example is nothing but a method of surgery of humans since it corresponds to a method for operating a manipulator and incising the affected part for the treatment of the affected part. Accordingly, the claimed method includes a method of surgery of humans as part of the steps of the invention; thus, the method is considered to be “methods of surgery, therapy or diagnosis of humans”

[Remark]

It should be noted that, if the claim is described as in Example 8-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 8-2 A method for controlling the operation of a micro operation robot system (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a micro operation robot system provided with a micro operation robot and a remote operation device for remote-operating the robot with a manipulator, wherein the robot has at its head an optical observing means and an incising means and at its bottom a receiving means for receiving manipulator signals from the remote operation device, comprising the steps of;

transmitting the signal of the manipulator by the transmitting device to the remote operation device, receiving the manipulator signal from the remote operation device by the receiving means of the robot, and controlling the operation of the incising means of the robot with the manipulator signal received.

Outline of Detailed Explanation of the Invention

The capsule type micro operation robot of the present invention can, owing to very delicate constitution thereof, perform treatment of the affected part by remote control in an organ such as a blood vessel or the like, without excessively burdening the patient.

[Explanation]

In this example, the function of the micro operation robot system is represented as a method.

Since the matter reading “controlling the operation of the incising means of the robot with the signal received” means that “the incising means” provided with the micro operation robot system is controlled with the manipulator signal received and does not mean so far that the incising means incise the human body as a result of the operation; thus, the claimed method is judged not to include the step with an influence on the human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method, and the method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. As a result, it is not considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

(1) A micro operation robot system is generally designed to be operated based on a manipulator signal operated by a medical doctor and is assumed to be operated by an action of a medical doctor. However, in case the function of the micro operation robot system is described as a method in a claim, it is considered as a method for controlling the operation of the micro operation system as long as it does not include the step with an action of a medical doctor and/or the step with an

influence on the human body by the device.

(2) Even if the function of the medical device is described as a method in a claim, it should be noted that the claim may not meet the requirement of description or embodiment if the device is not disclosed in the description, as in the case where only a method carried out by the step with an action of a medical doctor is disclosed.

Example 9-1 A method for sampling body fluid (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for sampling body fluid by a body fluid sampling device provided with a hollow piercing element installed inside housing, a sample extracting tube communicating with the piercing element, and an absorbing means, wherein the piercing element pierces the vein, and the body fluid is absorbed by the piercing element arranged in the vein blood vessel into the sample extracting tube.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for sampling body fluid such as blood or the like from the human body for analysis or processing. The housing of the body fluid sampling device is placed on the human body and a piercing element is pierced into the surface of the skin. When the device is operated, an absorbing power is applied to the piercing element to absorb the body fluid into the tube.

[Explanation]

The step of “the piercing element is pierced” is not carried out by a means provided with this fluid sampling device but is the step with an action of a medical doctor. (Note: In this case, the method may also be judged to include the step with an influence on the human body via the piercing element.)

The step of “the body fluid is absorbed from the piercing element arranged in the vein blood vessel into the sample extracting tube” is judged to include the step with an influence on the human body by the device, as a signal is not received from the human body but body fluid is extracted from the human body.

The claimed method, therefore, is not a method for controlling the operation of the medical device because it includes the step with an action of a medical doctor and the step with an influence on the human body by a device.

The claimed method includes the step of surgical operation of piercing human body with the piercing element. Accordingly, the claimed method includes methods of surgery of humans; thus, the method is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 9-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 9-2 A method for controlling the operation of a body fluid sampling device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a body fluid sampling device provided with a hollow piercing element installed inside a housing, a sample extracting tube communicating with the piercing element, a sampling vessel connected with the end of the tube and having a pressure detecting unit inside, and a negative pressure generating unit giving a negative pressure on the sampling vessel, wherein a suppressing means controlling the operation of the negative pressure generating means is operated when the pressure detecting means detects a pressure lower than the predetermined value in the operation of the negative pressure generating unit.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for sampling body fluid such as blood or the like from a human body for analysis or processing. The housing of the body fluid sampling device is placed on a human body and a piercing element is used to pierce the surface of the skin. When the device is operated, an absorbing power is applied to the piercing element to absorb the body fluid into the tube for sampling. In this invention, as the pressure detecting means and the suppressing means are provided in the sampling vessel, it becomes possible to avoid endangering a human body by preventing the application of a higher absorbing pressure than required.

[Explanation]

In this example, the function of the body fluid sampling device is represented as a method.

The matter reading “a suppressing means controlling the operation of the negative pressure generating means is operated when the pressure detecting means detects a pressure lower than the predetermined value in the operation of the negative pressure generating unit” means that the “suppressing means” provided with the body fluid sampling device is operated and does not mean so far that the volume of the body fluid absorbed is changed as a result of the operation of the suppressing means, and the claimed method is judged not to include the step with an influence on the human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method, and the method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. As a result, the method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 10-1 A method for the observation of the celom by using an endoscope (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for capturing images of the inside of the celom with an endoscope, by way of changing the direction of the view by the operator using the rotation indicator, and rotating the imaging unit whose light axis tilted to the insertional axis of the endoscope.

Outline of Detailed Explanation of the Invention

This invention relates to an endoscope for optical observation by insertion into the human body. It is especially beneficial to alter the direction of the view of rigid scopes such as laparoscopes that do not have a curve.

The endoscope of this invention has an external cylinder made of stainless pipe for the entire length of the insertion section, and is equipped with a imaging unit with a lens and a solid image sensor. The light axis of the imaging unit is tilted to the axis of the external cylinder and can rotate on the same axis as the external cylinder.

The imaging unit is rotated by a stepping motor. When an operator sends a signal indicating the rotation angle to the stepping motor by using the rotation indicator, the stepping motor rotates according to the signal and the operator can gain the desired visual field.

[Explanation]

Since the matter reading “the operator using the rotation indicator” includes the step with an action of a medical doctor, the claimed method is not considered as “methods for controlling the operation of a medical device.”

Since the claimed method does not involve the step with medical doctor’s judgment on the physical condition of a human body such as disease or physical health, the method is not considered as “methods of diagnosis of humans.”

However, the claimed method includes the step to operate the endoscope inside the human body, by rotating the imaging unit and changing the direction of the view, and it is described in the detailed explanation of the invention that the endoscope is inserted into the human body. Furthermore, the imaging with an endoscope is normally carried out with the endoscope placed inside the human body. Since the claimed method includes a method of surgery of humans as a part of the invention, the method is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 10-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 10-2 A method for controlling the operation of an endoscope (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of an endoscope, wherein means of rotating the imaging unit whose light axis is tilted to the insertional axis of the endoscope is operated by receiving an instruction signal to rotate.

Outline of Detailed Explanation of the Invention

This invention relates to an endoscope for optical observation by insertion into the human body. It is especially beneficial to alter the direction of the view of rigid scopes such as laparoscopes that do not have a curve.

The endoscope of this invention has an external cylinder made of stainless pipe for the entire length of the insertion section, and is equipped with a imaging unit with a lens and a solid image sensor. The light axis of the imaging unit is tilted to the axis of the external cylinder and can rotate on the same axis as the external cylinder.

The imaging unit is rotated by a stepping motor. When an operator sends a signal indicating the rotation angle to the stepping motor by using the rotation indicator, the stepping motor rotates according to the signal and the operator can gain the desired visual field.

[Explanation]

The matter reading “means of rotating the imaging unit whose light axis is tilted towards the insertional axis of the endoscope is operated by receiving an instruction signal to rotate” means that the means provided with the endoscope itself is operated by receiving an instruction signal to rotate, but it does not mean so further that a medical doctor gives the instruction signal to rotate, and the claimed method is judged not to include the step with an action of a medical doctor. Further, the claimed method does not include the step with an influence on the human body by the endoscope.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method, and is not considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

The statement of the claim of this example reads “A method for controlling the operation of an endoscope, wherein...” at the front, compared to that of Example 10-1. Additionally, the subject of the step of “is operated” is “means of rotating the imaging unit whose light axis is tilted to the insertional axis of the endoscope.”

Example 11-1 A method for contrast magnetic resonance imaging (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for contrast magnetic resonance imaging, wherein an examinee injected with contrast media is imaged with low-resolution real-time mode and then the mode is shifted to the actual high-resolution imaging when the signal strength within the desired domain exceeds the threshold value drastically.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for magnetic resonance imaging in accordance with the movement of contrast media.

The total dose of contrast media is determined by the patient’s weight, and the change in the infusion rate is determined depending on the part of the body to be imaged and the imaging method. The determined dose of contrast agent and the change in the infusion rate are then read into the power injector, and contrast media is injected into the examinee’s artery or venous during the imaging procedure. In order to obtain the image when the contrast agent reaches the desired domain, a real time image is acquired at low-resolution mode which enables a high time-resolution monitoring after the start of the contrast media injection. During the real time imaging procedure, the contrast magnetic resonance imaging device will continuously monitor the signal strength within the desired domain, and when the value exceeds the predetermined threshold value, the contrast magnetic resonance imaging device will detect that the contrast media has reached the desired domain and the mode is shifted to the actual imaging procedure of high-resolution setting.

[Explanation]

Since the claimed method does not represent the function of the medical device but the steps with an action of a doctor, the method is not deemed as “methods for controlling the operation of a medical device.”

The method in this example is not considered to be “methods of diagnosis of humans,” since it does not include the steps of medical doctors judging the condition of human diseases or the physical condition of a human body for medical purposes.

In addition because the claim reads “an examinee injected with contrast media” the claimed invention is not defined by the procedure of contrast media injection. However, as the detailed explanation of the invention reads “injected into the examinee’s artery or venous during the imaging procedure,” a surgical treatment of injecting contrast media into blood vessels is practiced during the imaging procedure of the claimed method.

Therefore, although “an examinee injected with contrast media” is stated in the claim as if the contrast media was injected before the imaging, the claimed method is considered as “methods of surgery, therapy or diagnosis of humans” since a surgical treatment is practiced in working of the claimed method and it includes a method of surgery of humans as a part of the step of the invention.

[Remark]

It should be noted that, if the claim is described as in Example 11-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 11-2 A method for controlling a magnetic resonance imaging device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a magnetic resonance imaging device, wherein means of shifting to high resolution imaging is operated by the device when the signal strength within the desired domain drastically changes from the threshold value.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for magnetic resonance imaging in accordance with the movement of contrast media.

The total dose of contrast media is determined by the patient’s weight, and the change in the infusion rate is determined depending on the part of the body to be imaged and the imaging method. The determined dose of contrast agent and the change in the infusion rate are then read into the power injector, and contrast media is injected into the examinee’s artery or venous during the imaging procedure. In order to obtain the image when the contrast agent reaches the desired domain, a real time image is acquired at low-resolution mode which enables a high time-resolution monitoring after the start of the contrast media injection. During the real time imaging procedure, the contrast magnetic resonance imaging device will continuously monitor the signal strength within the desired domain, and when the value exceeds the predetermined threshold value, the contrast magnetic resonance imaging device will detect that the contrast media has reached the desired domain and the mode is shifted to the actual imaging procedure of high-resolution setting.

[Explanation]

The claimed method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. The operation of the magnetic resonance imaging device to shift to high resolution imaging when the signal strength within the desired domain drastically changes from the threshold value, i.e., the function of the magnetic resonance imaging device, is represented as a method.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device and is not considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

The statement of the claim of this example reads “A method for controlling the operation of a magnetic resonance imaging device, wherein...” at the front, compared to that of Example 11-1. Additionally, the subject of the step of “is operated” is “magnetic resonance imaging device.”

Example 12-1 A method for displaying superimposed images of an object being cut and a cutting apparatus (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for displaying superimposed images of the three-dimensional data of an object being cut and the three-dimensional data of a cutting apparatus, comprising;

a step of obtaining the three-dimensional data of an object to be cut and a cutting device with markers attached, a step of detecting the position of the markers on the object to be cut and the cutting device, and a step of making a connection between the three-dimensional data of the object being cut and the three-dimensional data of the cutting device by calculating the relative positioning data of the object being cut and the cutting device.

Outline of Detailed Explanation of the Invention

The invention relates to a method for displaying superimposed images of an object being cut and a cutting device.

During a surgical operation for cutting bone or treating caries tooth, the image of the bone or the tooth can be displayed as superimposed images on the screen adjacent to the surgeon, thereby providing the surgeon with information regarding the progress of the surgical procedure. By observing the images on the screen, the surgeon can check accurately even sections that are difficult to view, and hence can carry out the surgery appropriately.

[Explanation]

A method for displaying superimposed images of an object being cut and a cutting device defined in the claim is a method to indicate a situation of cutting bone or treating caries tooth, and includes a method for cutting the bone or tooth.

Therefore, the claimed method includes a method of surgery or therapy of humans as a part of the steps of the invention; thus the method is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 12-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 12-2 A method for controlling a device for displaying superimposed images of an object being cut and a cutting apparatus (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a device for displaying superimposed images of the three-dimensional data of an object being cut and the three-dimensional data of a cutting apparatus, comprising;
a step for obtaining the three-dimensional data of an object to be cut and a cutting device with markers attached by means to obtain the image data, a step for detecting the position of the markers on the object to be cut and the cutting device by means to detect the position of the markers, and a step for making a connection between the three-dimensional data of the object being cut and the three-dimensional data of the cutting device with calculating the relative positioning data of the object being cut and the cutting device by means to make a connection.

Outline of Detailed Explanation of the Invention

The invention relates to a method for displaying superimposed images of an object being cut and a cutting device.

During a surgical operation for cutting bone or treating caries tooth, the image of the bone or the tooth can be displayed as superimposed images on the screen adjacent to the surgeon, thereby providing the surgeon with information regarding the progress of the surgical procedure. By observing the images on the screen, the surgeon can check accurately even sections that are difficult to view, and hence can carry out the surgery appropriately.

[Explanation]

The claimed method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. The function of the device for displaying superimposed images of the three-dimensional data of an object being cut and the three-dimensional data of a cutting device is represented as a method.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device and is not considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

The statement of the claim of this example reads “A method for controlling the operation of a device for...” at the front, compared to that of Example 12-1. Additionally, the subjects of the steps are “means to obtain the image data”, “means to detect the position of the markers” and “means to make a connection.”

4.2.2 Methods of therapy of humans

Example 13-1 A method for the treatment of cancer (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for treatment of cancer using;
a micro capsule X which contains an anti-cancer agent and releases the agent when disintegrated by a convergence supersonic wave, and
an apparatus having means to obtain the image data showing the position of the tumor, means to focus the convergence supersonic wave on the position of the tumor, and means to irradiate the convergence supersonic wave onto the micro capsule X.

Outline of Detailed Explanation of the Invention

This invention is directed to a method for treatment of cancer comprising injecting a micro capsule X with a anti-cancer agent inside into the blood vessel, destroying the micro capsule X in the body, and making the anticancer agent work efficiently on the tumor. Since the convergence supersonic wave is focused onto the position of the tumor, only the micro capsule that has reached the tumor is disintegrated and thus the anti-cancer agent can be effectively administered to the tumor.

[Explanation]

The method is to make an anticancer agent work on the tumor for treatment and falls under “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 13-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 13-2 A system for cancer treatment (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A cancer treatment system comprising;
a micro capsule X which contains an anti-cancer agent and releases the agent when disintegrated by a convergence supersonic wave, and
an apparatus having means to obtain the image data showing the position of the tumor, means to focus the convergence supersonic wave on the position of the tumor, and means to irradiate the convergence supersonic wave onto the micro capsule X.

Outline of Detailed Explanation of the Invention

The present invention relates to a system for effectively administering an anti-cancer agent to the tumor.

Since the convergence supersonic wave is focused onto the position of the tumor when the micro capsule X which contains an anti-cancer agent and has been injected into the blood vessel disintegrates inside the human body, only the micro capsule that has reached the tumor is disintegrated and thus the anti-cancer agent can be effectively administered to the tumor.

[Explanation]

The claimed treatment system is an invention of the combination of the micro capsule X, and the apparatus having the means to obtain the image data, the means to focus the convergence supersonic wave on the position of the tumor, and means to irradiate supersonic waves; hence it is a product invention. Therefore, it is not considered as “methods of surgery, therapy or diagnosis of humans.”

Example 14-1 A method for regenerating cartilage (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for regenerating cartilage wherein a material wherein the A-cells is embedded in gel formed by the biocompatible polymeric material Z is transplanted to a joint of humans.

Outline of Detailed Explanation of the Invention

It was found that transplantation of a material wherein the A-cells is embedded in gel formed by the biocompatible polymeric material Z to a joint of humans has a remarkable cartilage regenerating effect.

[Explanation]

The claimed invention is a method for regenerating cartilage and thus a method of therapy of humans. Also the claimed invention is a method to transplant a medical material into the body and thus a method of surgery of humans. Therefore, the claimed invention is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 14-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 14-2 An implant material for cartilage regeneration (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

An implant material for regenerating a cartilage consisting of biocompatible polymeric material Z and A-cells wherein the A-cells are embedded in gel formed by the biocompatible polymeric material Z, characterized in that the implant is transplanted to a joint of humans.

Outline of Detailed Explanation of the Invention

It was found that transplantation of a material wherein the A-cells is embedded in gel formed by the biocompatible polymeric material Z to a joint of humans has a remarkable cartilage regenerating effect.

[Explanation]

As the implant material for cartilage regeneration described in the claim itself is a product, it does not fall under “methods of surgery, therapy or diagnosis of humans.”

Example 15-1 A method for the treatment of cardiac infarction (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for treating cardiac infarction wherein A-cells and cell growth factor W are combined to be administrated to the site of cardiac infarction of humans.

Outline of Detailed Explanation of the Invention

It was found that the infarct area was reduced and cardiac function was recovered by injecting a combination of A-cells and cell growth factor W to the site of cardiac infarction of humans.

[Explanation]

As the claimed method is for treating myocardial infarction, it is a method of therapy of humans. Also as the claimed method involves a method for administering A-cells and cell growth factor W to the site of cardiac infarction, it is a method of surgery of humans. Therefore, the claimed invention falls under “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 15-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 15-2 A composition for treatment of cardiac infarction (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A composition for treating cardiac infarction containing A-cells and cell growth factor W as active ingredients, characterized in that the composition is administered to the site of cardiac infarction of humans.

Outline of Detailed Explanation of the Invention

It was found that the infarct area was reduced and cardiac function was recovered by injecting a combination of A-cells and cell growth factor W to the site of cardiac infarction of humans.

[Explanation]

As the composition for treating cardiac infarction described in the claims itself is a product, it does not fall under “methods of surgery, therapy or diagnosis of humans.”

Example 16-1 A method for giving electrical stimulus by a pacemaker (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for giving an electrical stimulus by a pacemaker, comprising;
a step of comparing a heart rate detected by a detecting unit with a threshold value stored in a memory device, and, when the heart rate is lower than the threshold value,

a step of reading out an average heart rate in a steady state from the memory device, a step of calculating the difference between the average heart rate and the detected heart rate, a step of setting a pulse generating interval value in accordance with the difference, a step of a pulse generating unit's giving stimulus to the ventricle of the heart with the pulse generating interval having been set, and a step of keeping the heart rate steady.

Outline of Detailed Explanation of the Invention

Since the pacemaker constantly analyzes an electric signal from a myocardium to give a stimulus to the ventricle of the heart with a signal most fitted to the state of the heart, the maintenance of the optimum heart rate is made possible without a switching operation of the output signal.

[Explanation]

Since the matter reading “giving stimulus to the ventricle of the heart, and keeping the heart rate steady” includes the step with an influence on the human body by the device, the claimed method is not considered to be a method for controlling the operation of the medical device.

The method in this example is considered to be a method of therapy of humans, since it corresponds to a method for curing diseases by giving a stimulus to the ventricle of the patient's heart with pacemaker pulses and maintaining an optimum heart rate. Accordingly, the claimed method includes a method of therapy of humans as a part of the steps of the invention; thus, the method is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 16-2 to 16-4, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 16-2 A method for controlling a pacemaker (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling a pacemaker, comprising;
a step of comparing a heart rate detected at a detecting unit with a threshold value stored in a memory, and, when the heart rate is lower than the threshold value,
a step of reading out an average heart rate in a steady state from the memory, a step of calculating the difference between the average heart rate and the detected heart rate, and a step of setting a pulse generating interval value in accordance with the difference.

Outline of Detailed Explanation of the Invention

Since the pacemaker constantly analyzes an electric signal from a myocardium to set a generating interval of the pulses most fitted to the state, the maintenance of an optimum heart rate is made possible.

[Explanation]

In this example, the method relates to a method for controlling the internal operation of a pacemaker, and the function of the medical device is represented as a method.

Additionally, no step involves the step with an action of a medical doctor on a human body or the step with an influence on a human body by a device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device and is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 16-3 A method for controlling a pacemaker (An invention method not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling a pacemaker, comprising;
a step of comparing a heart rate detected at a detecting unit with a threshold value stored in a memory, and, when the heart rate is lower than the threshold value,
a step of reading out an average heart rate at a steady state from the memory, a step of calculating the difference between the average heart rate and the detected heart rate, a step of setting a pulse generating interval value in accordance with the difference, and a step of the pulse generating means' generating pulses for giving stimulus to the ventricle of the heart with the pulse generating interval.

Outline of Detailed Explanation of the Invention

Since the pacemaker constantly analyzes electrical signals from the myocardium to set the generating interval of the pulses most fitted to the state, the maintenance of an optimum heart rate is made possible.

[Explanation]

In this example, the function of the pacemaker is represented as a method, and, in addition to the method for controlling the internal operation of the pacemaker as described in Example 16-2, this method includes the step of generating pulses toward the outside of the pacemaker.

The matter reading “the pulse generating means' generating pulses for giving stimulus to the ventricle of the heart with the pulse generating interval” means that “the pulse generating means” provided with the pacemaker generates pulses, but it does not mean so far that the generated pulses give stimulus to the ventricle of the heart as the direct result of the pulses being generated; thus, it is judged not to have the step with an influence on the human body by the device.

It should be further noted that pulses “for giving stimulus to the ventricle of the heart” does not depict the step with an influence on the human body, since it specifies the state and/or the character of the pulse and differs from an influence on the human body of giving stimulus to the ventricle of the heart.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method and does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. As a result, the method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

A pacemaker is generally designed to be placed and operated in the human body by nature and is assumed to operate in a human body. However, in case the function of the pacemaker is described as a method in a claim, it is considered

as a method for controlling the operation of the pacemaker as long as the method does not include the step with an action of a medical doctor and/or the step with an influence on the human body by the device.

Example 16-4 A method for controlling the operation of a pacemaker (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a pacemaker; wherein means for comparing a heart rate detected in a detecting unit with a threshold value stored in a memory is operated, and, when the heart rate is lower than the threshold value, means for reading out an average heart rate at a steady state from the memory is operated, means for calculating the difference between the average heart rate and the detected heart rate is operated, means for setting the pulse generating interval value in accordance with the difference is operated, and pulse generating means for generating pulses for giving stimulus to the ventricle of the heart with a set pulse generating interval is operated.

Outline of Detailed Explanation of the Invention

Since the pacemaker constantly analyzes electrical signals from a myocardium to set the pulse-generating interval best fitted to the state of the heart, the maintenance of the optimum heart rate is made possible.

[Explanation]

In this example, the function of the pacemaker is represented as a method.

The matter reading “pulse generating means for generating pulses for giving stimulus to the ventricle of the heart is operated” means that “the pulse generating means” provided with the medical device is operated, but it does not mean so far that the generated pulses give stimulus to the ventricle of the heart as the direct result of “the pulse generating means” being operated and the claimed method is judged not to include the step with an influence on the human body.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method, and does not include the step with an action of a medical doctor on the human body or the step with an influence on the human body by the device. As a result, the method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 17-1 A method for retinal stimulation using an artificial eye system (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for giving stimulus to a retina by an artificial eye system provided with an extracorporeal device composed of a visor device having an image receiving element and a light emitting element, and an extracorporeal image processing device, and an intraocular devices having a light receiving element, a signal processing circuit and an electrode, comprising; a step of making a picture signal by processing an outside picture image obtained from the image receiving element of the visor device, a step of converting the picture signal into an optical signal for transmitting from the light emitting element of the visor device to the light receiving element of the intraocular devices, a step of receiving the optical signal by the light receiving element of the intraocular devices installed inside the oculus, a step of converting the received signal into a signal for use in electrical stimulation by the signal processing circuit of the intraocular devices, and a step of transmitting the signal for use in the electrical stimulation to an electrode for retina to transfer the signal to the retina, wherein stimulus of the picture information is given to the retina of the patient by the artificial eye system.

Outline of Detailed Explanation of the Invention

The artificial eye system of the present invention can transfer the signal of the artificial picture information to the retina of a visually handicapped patient through an electrode for retina buried in the retina, by combining the image receiving element, the light emitting element, the light receiving element, and the signal processing circuit.

[Explanation]

The matter reading “transmitting the signal for use in electrical stimulation to an electrode for retina to transfer the signal to the retina” includes the step with an influence on the human body by the device as it transfers the signal to the retina resulting in the electrical stimulation of the retina.

In addition, the matter reading “stimulus of the picture information is given to the retina of the patient” depicts the step with an influence on the human body by the device giving stimulus to the retina of the patient.

The claimed method, therefore, is not considered to be a method for controlling the operation of the medical device.

The method in this example is considered to be a method of therapy of humans, since it corresponds to a method for recovering the visual functions of a patient to cure diseases by transferring the signal for use in the electrical stimulation to the retina of a patient with the artificial eye system.

Accordingly, the claimed method includes a method of therapy of humans as a part of the steps of the invention; thus, it is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 17-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 17-2 A method for controlling an artificial eye system (An invention method not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling an artificial eye system provided with an extracorporeal device composed of a visor device having an image receiving element and a light emitting element, and an extracorporeal image processing device, and an intraocular device having a light receiving element, a signal processing circuit and an electrode, comprising;
a step of making a picture signal by processing an outside picture image by the image receiving element of the visor device, a step of converting the picture signal into an optical signal for transmitting from the light emitting element of the visor device to the light receiving element of the device for intraocular use, a step of receiving the optical signal by the light receiving element of the devices for intraocular use, a step of converting the received signal into a signal for use in the electrical stimulation for transferring to the retina by the signal processing circuit of the device for intraocular use, and a step of transmitting the signal for use in the electrical stimulation to the electrode buried in the retina.

Outline of Detailed Explanation of the Invention

The artificial eye system of the present invention can transfer the signal of the artificial picture information to the retina of a visually handicapped patient through an electrode buried in the retina, by combining the image receiving element, the light emitting element, the light receiving element, and the signal processing circuit.

[Explanation]

In this example, the function of the artificial eye system is represented as a method.

Since the matter reading “transmitting the signal for use in the electrical stimulation to the electrode buried in the retina” means that the device for intraocular use transmits signals for use in electrical stimulation and does not mean so far as transferring the signal for use in the electrical stimulation to the retina as the result of the transmission, the claimed method is judged not to include the step with an influence on the human body by the device.

It should be noted that the matter reading “buried in the retina” in the above step specifies the state and/or the character of the electrode in the artificial eye system and is distinguished from the step with the action of a medical doctor burying the electrode in the retina or from the step with an influence on the human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of the medical device since the function of the medical device is represented as a method and does not include the step with an action of a medical doctor on the human body or the step with an influence on the human body by the

device. As a result, it is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 18-1 A method for X-ray irradiation (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for irradiating X-rays onto the human body by changing the tube voltage and the tube current of the X-ray generator each time the generator rotates one lap inside the gantry.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for treatment of the human body by X-ray therapy with confirming the X-ray therapy process by monitoring the X-ray image of the affected area.

The device used in the current invention places the X-ray generator and the X-ray detector in opposite positions inside the gantry, and rotates one lap around the circumference of the gantry maintaining the opposite positions. The X-ray generator which is used for treatment of the human body and imaging procedures sets the appropriate tube voltage and tube current for treatment at the time of treatment and sets the appropriate tube voltage and tube current for image processing at the time of imaging. The X-ray device used in this invention has a control function for controlling the operation of the X-ray generator and the X-ray detector, and their rotation, detects the rotating position of the X-ray generator, and changes the tube voltage and tube current each time it rotates one lap around the circumference.

In the present invention the treatment and the imaging procedures are switched over each time the X-ray generator and the X-ray detector rotates one lap inside the gantry. At the time of treatment the X-ray will be irradiated to the affected area at the appropriate tube voltage and tube current value for treatment procedures while the X-ray generator is rotating one lap around the circumference. Just before the start of the next lap, the value of the tube voltage and tube current is changed to the appropriate value for imaging. During the next lap, the X-ray will be irradiated to the affected area at the appropriate tube voltage and tube current value for imaging, the X-ray that penetrate the affected area are detected by the X-ray detector, and image reconstruction is performed.

[Explanation]

Since the matter reading “irradiating X-rays onto the human body” includes the step with an influence on the human body by the device, the claimed method is not considered to be a method for controlling the operation of the medical device.

Additionally since the claimed method does not include the steps with an action of a medical doctor judging the condition of human diseases or the physical condition of a human body for medical purposes, it is not considered to be “methods of diagnosis of humans.”

According to the detailed explanation of this invention, by changing the tube voltage and tube current of the X-ray generator, the treatment and imaging is repeated alternately; thus the steps to irradiate X-rays onto the human body by changing the tube voltage and tube current of the X-ray generator include a step of therapy of humans. Therefore, the claimed method is considered to be “methods of surgery, therapy or diagnosis of humans.”

[Remark]

It should be noted that, if the claim is described as in Example 18-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 18-2 A method for operating an X-ray device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the X-ray generator by control means of the X-ray device; wherein the control means change the tube voltage and the tube current of the said X-ray generator each time the generator rotates one lap inside the gantry.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for treatment of the human body by X-ray therapy with confirming the X-ray therapy process by monitoring the X-ray image of the affected area.

The device used in the current invention places the X-ray generator and the X-ray detector in opposite positions inside the gantry, and rotates one lap around the circumference of the gantry maintaining the opposite positions. The X-ray generator which is used for treatment of the human body and imaging procedures sets the appropriate tube voltage and tube current for treatment at the time of treatment and sets the appropriate tube voltage and tube current for image processing at the time of imaging. The X-ray device used in this invention has a control function for controlling the operation of the X-ray generator and the X-ray detector, and their rotation, detects the rotating position of the X-ray generator, and changes the tube voltage and tube current each time it rotates one lap around the circumference.

In the present invention the treatment and the imaging procedures are switched over each time the X-ray generator and the X-ray detector rotates one lap inside the gantry. At the time of treatment the X-ray will be irradiated to the affected area at the appropriate tube voltage and tube current value for treatment procedures while the X-ray generator is rotating one lap around the circumference. Just before the start of the next lap, the value of the tube voltage and tube current is changed to the appropriate value for imaging. During the next lap, the X-ray will be irradiated to the affected area at the appropriate tube voltage and tube current value for imaging, the X-ray that penetrate the affected area are detected by the X-ray detector, and image reconstruction is performed.

[Explanation]

The claimed method does not include the step with an action of a medical doctor on the human body or the step with an influence on the human body by the device. The operation of the X-ray generator by control means of the X-ray device, i.e. the function of the X-ray device, is represented as a method.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device and is not considered to be “methods of surgery, therapy or diagnosis of humans.”

4.2.3. Methods for gathering data

Example 19-1 A method for X-ray CT scanning (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for imaging by controlling the respective parts of an X-ray CT scanner by control means, comprising;
a step of exposing X-rays to the human body by controlling X-ray generating means, a step of detecting the X-rays permeated through the human body by controlling X-ray detecting means, and a step of performing reconstruction of the detected data and converting such detected data into picture data for display.

Outline of Detailed Explanation of the Invention

The present invention relates to a method for imaging by controlling an X-ray CT scanner for picking up an image of a human body, and a picture image thereof can be accurately displayed on account of the reconstruction of the detected data.

[Explanation]

The claimed invention does not include the steps of medical doctors judging for medical purposes the physical condition of a human body such as diseases and physical health, nor the steps of surgery or therapy of humans. Therefore, the claimed method is not considered as “methods of surgery, therapy or diagnosis of humans.”

[Remark]

Since the matter reading “exposing X-rays to the human body” includes the step with an influence on the human body by the device, the claimed method is not considered to be a method for controlling the operation of the medical device.

Example 19-2 A method for controlling an X-ray CT scanner (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the respective parts of an X-ray CT scanner by control means, comprising;
a step of generating X-rays by controlling X-ray generating means, a step of detecting X-rays permeated through the human body by controlling X-ray detecting means, and a step of performing reconstruction of the data detected and converting the detected data into picture data for display.

Outline of Detailed Explanation of the Invention

The present invention relates to a method of controlling an X-ray CT scanner for picking up an image of a human body, and a picture image thereof can be accurately displayed on account of reconstruction of the detected data.

[Explanation]

In this example, the function of the X-ray CT scanner is represented as a method.

Since the matter reading “generating X-rays by controlling X-ray generating means” means that the “X-ray generating means” belonging to the X-ray CT scanner generates X-rays and does not mean so far that the human body is exposed by the X-rays; thus, the claimed method is judged not to include the step with an influence on the human body by the device.

Furthermore, the matter reading “detecting X-rays permeated through the human body by controlling X-ray detecting means” represents the function that the “X-ray detecting means” provided to the X-ray CT Scanner receives a signal (X-ray) permeated through a human body. As a result, the claimed method is judged not to include the step with an action of a medical doctor or the step with an influence on a human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method, and the method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. Accordingly, the method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 20-1 A method for magnetic resonance imaging (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for magnetic resonance imaging by a magnetic resonance imaging device comprising;
a step of repeating pulse sequences while sequentially changing the intensity of the gradient magnetic field in the phase encode direction in the order from lower to higher, wherein the pulse sequence is carried out by irradiating 90° pulse to the imaging objective region while generating a gradient magnetic field in the slice direction, a step of generating a predetermined quantity of the gradient magnetic field in the phase encode direction, a step of irradiating 180° pulse to the region while generating the gradient magnetic field in the slice direction, and a step of detecting a magnetic resonance signal from the pertinent region while generating the gradient magnetic field in the lead-out direction.

Outline of Detailed Explanation of the Invention

The magnetic resonance imaging device of the present invention acquires magnetic resonance signals in the order of phase encode from low to high when the human body is imaged by the spin-echo method.

[Explanation]

The claimed invention do not include the steps of medical doctors judging for medical purposes the physical condition of a human body such as diseases and physical health, nor the steps of surgery or therapy of humans. Therefore, the claimed method is not considered as “methods of surgery, therapy or diagnosis of humans.”

[Remark]

Since the matters reading “irradiating 90° pulse to the imaging objective region while generating a gradient magnetic field in the slice direction” and “irradiating 180° pulse to the region while generating the gradient magnetic field in the slice direction” include the step with an influence on the human body by the device, the claimed method is not considered to be a method for controlling the operation of the medical device.

Example 20-2 A method for controlling magnetic resonance imaging device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a magnetic resonance imaging device in which the control means of the magnetic resonance imaging device controls a transmitting and receiving circuit, a RF coil, and a gradient coil, comprising; a step of repeating pulse sequences while sequentially changing the intensity of the gradient magnetic field in the phase encode direction in the order from low to high, wherein the pulse sequence is carried out by a RF coil transmitting a 90° pulse toward a uniform magnetic field space while the gradient coil is generating the gradient magnetic field in the slice direction, a step of a gradient coil generating a predetermined quantity of the gradient magnetic field in the phase encode direction, a step of a RF coil transmitting an 180° pulse while the gradient coil is generating a gradient magnetic field in the slice direction, and a step of a RF coil receiving a magnetic resonance signal from a human body while a gradient coil is generating a gradient magnetic field in the read-out direction.

Outline of Detailed Explanation of the Invention

The magnetic resonance imaging device of the present invention acquires magnetic resonance signals in the order of the phase encode from low to high when a human body is imaged by a spin-echo method.

[Explanation]

In this example, the function of the magnetic resonance imaging device is represented as a method.

The matters reading “a RF coil transmitting a 90° pulse toward a uniform magnetic field space while the gradient coil is generating the gradient magnetic field” and “a RF coil transmitting 180° pulse while the gradient coil is generating the gradient magnetic field” mean that “the RF coils” provided with the magnetic resonance imaging device transmit pulses; however, this does not mean so far that the generated pulses are exposed to the human body as a result of generating pulses. Accordingly, the claimed method is judged not to include the step with an influence on the human body by the device.

Furthermore, the matter reading “the RF coil receiving a magnetic resonance signal from the human body” represents the function that “the RF coil” receives a signal (magnetic resonance signal) from the human body; thus, the claimed method is judged not to include the step with an influence on the human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method, and the method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. As a result, the method is not considered to be “methods of surgery, therapy or

diagnosis of humans.”

Example 21 A method for nuclear medicine imaging (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for nuclear medicine imaging comprising; a step of performing SPECT imaging synchronized with the cardiac cycle on the examinee’s heart administered with a radioactive agent, a step of performing ultrasonic Doppler imaging synchronized with the cardiac cycle on the examinee’s heart without contrast agent, and a step of superimposing of the SPECT image and the ultrasonic Doppler image that have the same time phase of the heartbeat.

Outline of Detailed Explanation of the Invention

The present invention relates to the superimposed image display of a SPECT (Single photon emission computed tomography) image which is a type of a nuclear medicine image and a supersonic Doppler myocardial image.

Firstly with regard to the myocardial SPECT imaging, a radioactive agent that contains gamma emitters such as Technetium is administered to the vein of the examinee, and 45 minutes later, the examinee is moved to the bed of the SPECT device. An electrocardiogram device is attached to the examinee and the SPECT imaging is performed in synchronization with the heartbeat.

Next, in order to avoid excess strain on the examinee’s heart, further use of radioactive agent are avoided and an electrocardiogram device is attached to the examinee and the Doppler myocardial imaging is performed in synchronization with the heartbeat.

The SPECT images and supersonic Doppler images that have the same time phase of the heartbeat are displayed in a superimposed display format.

The superimposed image displays enable the evaluation of cardiac ischemia, and because of the synchronization with the heartbeat, inconsistency in the data appearance due to pulsation can be avoided.

[Explanation]

In order to perform SPECT imaging, radioactive agent injection into the vein is required; however, the imaging is commenced after a time lapse according to the detailed explanation of the invention. No surgical procedure takes place during the steps of the claimed method. Furthermore, the claimed method does not include the steps of medical doctors judging the condition of human diseases or the physical condition of a human body for medical purposes.

Therefore, the claimed method is not considered as “methods of surgery, therapy or diagnosis of humans.”

[Remark]

Since the claimed method does not represent the function of the medical device but the steps with an action of a doctor, the method is not deemed as “methods for controlling the operation of a medical device.”

4.2.4 Methods for treating samples that have been extracted from the human body

Example 22-1 A method for Gene therapy (An invention considered as "methods of surgery, therapy or diagnosis of humans")

Claim

A method of reducing a cancer by administering the vector Z including both the DNA encoding protein X and the DNA encoding protein Y into a human body.

Outline of Detailed Explanation of the Invention

It was found that a cancer would be reduced as a result of suppression of angiogenesis particular to cancer tissues and simultaneously stimulation of immunity by administering the claimed recombinant vector into a human body.

[Explanation]

A method for the reducing cancer by administration of the recombinant vector into a human body is considered as methods of therapy of humans. Therefore, the claimed method is considered as "methods of surgery, therapy or diagnosis of humans."

Example 22-2 A method for manufacturing cell formulation for gene therapy (An invention not considered as "methods of surgery, therapy or diagnosis of humans")

Claim

A method for manufacturing cell formulation for cancer therapy by introducing genes with vector Z including both the DNA encoding protein X and the DNA encoding protein Y into a cell W extracted from a human body

Outline of Detailed Explanation of the Invention

It was found that a cancer would be reduced as a result of suppression of angiogenesis particular to cancer tissues and simultaneously stimulation of immunity by the recombinant cell medicine for cancer therapy obtained by the claimed method.

The cells obtained from a donor who is a relative of the patient could be used. However, it is the most preferable to use the cells from the patient himself or herself in view of compatibility.

[Explanation]

Methods for manufacturing medicines like recombinant cell medicines from the cells extracted from a human body as a raw material are not considered as "methods of surgery, therapy or diagnosis of humans," even if the cells extracted from the patient himself or herself are supposed to be used, as described in the detailed explanation of the invention.

Examples 23-1 A method of inducing differentiation of cells (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method of inducing differentiation of an human induced pluripotent stem cells to a neural stem cells wherein the human induced pluripotent stem cells are cultured in serum-free medium and in the presence of X cell growth factor.

Outline of Detailed Explanation of the Invention

It was found that the the differentiation of human induced pluripotent stem cells (hereinafter abbreviated as “iPS cells”) to neural stem cells was induced by culturing them in serum-free medium and in the presence of X cell growth factor.

Moreover, taking into consideration of immunological compatibility, it is preferable to use iPS cells derived from somatic cells of the same patient. The neural stem cells differentiated from human iPS cells can be used as a therapeutic agent for degenerative neurological disorder.

[Explanation]

Since the method of inducing differentiation to the neural stem cells outside the human body is applicable to "a method for manufacturing an intermediate product for a medicinal product or a medical material by utilizing raw materials collected from a human body," it does not fall under "methods of surgery, therapy or diagnosis of humans," even if the method is practiced on the presumption that the materials are to be returned to the same body.

Examples 23-2 A method of separating and purifying differentiation-induced cells (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method of separating and purifying neural stem cells from a cell population including them differentiated from human iPS cells, the said method comprising the steps of;

- (a) separating the neural stem cells by using separation membrane M, and
- (b) culturing the cells separated in (a) in the medium containing compound P.

Outline of Detailed Explanation of the Invention

It was found that the separation membrane M selectively absorbed the neural stem cells. Moreover, it has been publicly known that compound P is useful for maintaining pluripotency of the neural stem cells and for proliferation of them.

Thus, it is possible to obtain high-purity neural stem cells by separating the neural stem cells from the cell population containing undifferentiated human iPS cells and purifying them by using the separation membrane M, and by culturing them in the medium containing compound P. The high-purity neural stem cells can be used as a safer therapeutic agent for degenerative neurological disorder.

[Explanation]

Since the method of separating and purifying the neural stem cells outside the human body is applicable to "a method for manufacturing a intermediate product for medicinal product or a medical material by utilizing raw materials collected from a human body," it does not fall under "methods of surgery, therapy or diagnosis of humans," even if the method for treating materials is practiced on the presumption that the materials are to be returned to the same body.

Example 23-3 A method of analyzing a ratio of separated and purified cells (An invention method not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method of analyzing a ratio of neural stem cells within a cell population including separated and purified neural stem cells derived from human iPS cells, the said method comprising the steps of;

(a) measuring the expression level of cell marker A and cell marker B in the said cell population using a labeled antibody respectively, and

(b) determining the ratio of the neural stem cells based on the said expression level,

wherein the cell marker A consists of the amino-acid sequence of SEQ ID NO:1.

Outline of Detailed Explanation of the Invention

It was found that the cell marker A was specifically expressed in the neural stem cells and consisted of the amino acid sequence of SEQ ID NO:1. An antibody which binds to the cell marker A was also produced. Moreover, the cell marker B is publicly known as a cell marker widely expressing in the overall stem cells.

Thus, it is possible to measure the expression level of the cell marker A and the cell marker B using a labeled antibody respectively,, and to analyze the ratio of the neural stem cells in a cell population derived from the human iPS cells by deciding a determining the the expression level of the cell marker A to that of the cell marker B, which allows safer treatment of degenerative neurological disorder.

[Explanation]

Since the method of inspecting the separated and purified cell population outside the human body is applicable to "a method for analyzing a medicinal product or a medical material, or an intermediate product thereof which is manufactured by utilizing raw materials collected from a human body," it does not fall under "methods of surgery, therapy or diagnosis of humans," even if the method for treating materials is practiced on the presumption that the materials are to be returned to the same body.

Example 24-1 A method for blood purification (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for blood purification by a blood purifying device provided with a blood removal line, a blood return line, a blood plasma separation apparatus to separate the blood cell and blood plasma in the blood introduced through the blood removal line, a absorptive apparatus to remove any disease virus separated from the blood plasma, a pressure sensor to detect the pressure of the blood removal line and blood return line, and a blood pump, comprising;
a step of removing blood via the blood removal line, a step of separating the blood cell and the blood plasma, a step of removing any disease virus from the separated blood plasma, a step of mixing the blood cells with the blood plasma with the disease virus removed, a step of returning blood via the blood return line, and a step of controlling the flow of blood from the blood pump according to the pressure of the blood removal line and blood return line.

Outline of Detailed Explanation of the Invention

The blood purifying device of the present invention can perform treatment safely and continuously by controlling the flow of blood from the blood pump according to the pressure of the blood removal line and blood return line when removing any disease virus such as bilirubin from the blood.

[Explanation]

The matter reading “removing blood via the blood removal line” and “returning blood via the blood return line” are the step with an influence on the human body by a device.

The matters reading “separating the blood cell and the blood plasma,” “removing any disease virus from the separated blood plasma” and “mixing the blood cells with the blood plasma with the disease virus removed” mean that separating blood into the blood cell and the blood plasma, removing any disease virus from the separated blood plasma, and mixing the blood cells with the blood plasma with the disease virus removed are performed in an extracorporeal circuit; thus are deemed as the steps with an influence on the human body by a device.

The matter reading “controlling the flow of blood from the blood pump according to the pressure of the blood removal line and blood return line” means that the flow of blood from the blood pump is controlled; thus are deemed as the step with an influence on the human body by a device.

Therefore, the claimed method is not considered to be a method for controlling the operation of a medical device.

The method in this example is considered as “methods of surgery, therapy or diagnosis of humans,” since it corresponds to a method of treating the blood in an extracorporeal circuit, and is a method to treat a sample which has been extracted from the human body on the assumption that the sample is to be returned to the same human body for medical treatment purposes; thus it is considered as methods of therapy of humans.

[Remark]

It should be noted that, if the claim is described as in Example 24-2, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 24-2 A method for controlling the operation of a blood purifying device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling a blood purifying device provided with a blood removal line, a blood return line, a blood plasma separation apparatus to separate the blood cell and blood plasma in the blood introduced through the blood removal line, a absorptive apparatus to remove any disease virus separated from the blood plasma, a pressure sensor to detect the pressure of the blood removal line and blood return line, and a blood pump, wherein a means controlling the flow of the blood pump is operated according to the output from the pressure sensor.

Outline of Detailed Explanation of the Invention

The blood purifying device of the present invention can perform treatment safely and continuously by controlling the flow of blood from the blood pump according to the pressure of the blood removal line and blood return line when removing any disease virus such as bilirubin from the blood.

[Explanation]

In this example the function of the blood purifying device is represented as a method.

The matter reading “a means controlling the flow of the blood pump is operated according to the output from the pressure sensor” means that “the means controlling the flow of the blood pump” provided with the blood purifying device is operated, but it does not mean so further that there is a change in the blood output from the pump as a result, and it is judged not to include the step with an influence on the human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method and does not include the step with an action of a medical doctor on the human body or the step with an influence on the human body by the device. As a result, the method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 25-1 A method for measuring hematocrit values of blood (An invention considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for optically measuring hematocrit values of blood, the method comprising;
irradiating the blood with light comprising a selected range of wavelengths; and
calculating the hematocrit value based on the strength of the reflection from the blood.

Outline of Detailed Explanation of the Invention

The present invention relates to a method of measuring the blood hematocrit value, by utilizing the light absorbing characteristic of each element in blood, and calculating the blood hematocrit value.

This invention enables the measuring of the hematocrit value of blood flowing in the blood circuit during dialysis treatment. During a dialysis treatment the fluid removal rate has to be controlled so that the patient does not experience any blood pressure drop or shock. The hematocrit value of blood flowing in the blood circuit which is a parameter closely related to the rate of change of the circulating blood volume, which is a control factor for the fluid removal rate, can be calculated without direct contact with the circulating blood.

Other than measuring the hematocrit value of the blood during dialysis treatment, the present invention enables conducting of various tests such as anemia tests. In such cases, the extracted blood is housed in a test container, the blood housed in the test container is irradiated with light comprising a selected range of optical wavelengths, and the blood hematocrit value which is an indicator for anemia is calculated based on the strength of the reflection from the blood.

[Explanation]

Although the claimed method does not include a method for removing blood or returning blood, the method in this example corresponds to a method for measuring blood hematocrit values of blood in an extracorporeal circuit.

Accordingly the claimed method is deemed as “methods of surgery, therapy or diagnosis of humans,” since it corresponds to a method to analyze a sample which has been extracted from the human body on the assumption that the sample is to be returned to the same human body for medical treatment purposes.

[Remark]

It should be noted that, if the claim is described as in Example 25-2 and 25-3, the claimed invention is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 25-2 A method for measuring hematocrit values of extracted blood (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for optically measuring hematocrit values of blood which is housed in a test container, the method comprising; irradiating the blood with light comprising a selected range of wavelengths; and calculating the hematocrit value based on the strength of the reflection from the blood.

Outline of Detailed Explanation of the Invention

The present invention relates to a method of measuring the blood hematocrit value, by utilizing the light absorbing characteristic of each element in blood, and calculating the blood hematocrit value.

This invention enables the measuring of the hematocrit value of blood flowing in the blood circuit during dialysis treatment. During a dialysis treatment the fluid removal rate has to be controlled so that the patient does not experience any blood pressure drop or shock. The hematocrit value of blood flowing in the blood circuit which is a parameter closely related to the rate of change of the circulating blood volume, which is a control factor for the fluid removal rate, can be calculated without direct contact with the circulating blood.

Other than measuring the hematocrit value of the blood during dialysis treatment, the present invention enables conducting of various tests such as anemia tests. In such cases, the extracted blood is housed in a test container, the blood housed in the test container is irradiated with light comprising a selected range of optical wavelengths, and the blood hematocrit value which is an indicator for anemia is calculated based on the strength of the reflection from the blood.

In addition, the blood which is housed in a test container is discarded without returning to human body.

[Explanation]

The claimed method is considered to be a method for measuring the blood hematocrit value of blood which is housed in a test container, and does not include a method practiced in the extracorporeal circuit. As a result, it is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Example 25-3 A method for controlling the operation of a blood hematocrit measuring device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling the operation of a device for optically measuring blood hematocrit value, wherein; means of irradiating the blood with light comprising a selected range of wavelengths is operated; and means of calculating the hematocrit value based on the strength of the reflection from the blood is operated.

Outline of Detailed Explanation of the Invention

The present invention relates to a method of measuring the blood hematocrit value, by utilizing the light absorbing characteristic of each element in blood, and calculating the blood hematocrit value.

This invention enables the measuring of the hematocrit value of blood flowing in the blood circuit during dialysis treatment. During a dialysis treatment the fluid removal rate has to be controlled so that the patient does not experience any blood pressure drop or shock. The hematocrit value of blood flowing in the blood circuit which is a parameter closely related to the rate of change of the circulating blood volume, which is a control factor for the fluid removal rate, can be calculated without direct contact with the circulating blood.

Other than measuring the hematocrit value of the blood during dialysis treatment, the present invention enables conducting of various tests such as anemia tests. In such cases, the extracted blood is housed in a test container, the blood housed in the test container is irradiated with light comprising a selected range of optical wavelengths, and the blood hematocrit value which is an indicator for anemia is calculated based on the strength of the reflection from the blood.

[Explanation]

In this example the function of the device for optically measuring the blood hematocrit value is represented as a method.

The matter reading “means of irradiating the blood with light comprising a selected range of wavelengths is operated” means that “the means of irradiating with light comprising a selected range of wavelengths” provided with the blood purifying instrument is operated, but it does not mean so further that the light is irradiated to the human body as a result of the “the means of irradiating with light comprising a selected range of wavelengths” being operated and it is judged not to include the step with an influence on the human body by the device.

Therefore, the claimed method is considered to be a method for controlling the operation of a medical device since the function of the medical device is represented as a method and does not include the step with an action of a medical doctor on the human body or the step with an influence on the human body by the device. As a result, the method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

4.2.5. Methods relating to assisting devices

Examples 26-1 A method for judging a motion state of walking (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for judging walking conditions with a power assisting equipment coupled to a leg of a worker to reduce his burden comprising,
a step of measuring myogenic potential of the leg of the worker by a sensor attached to a leg part of the power assisting equipment, and
a step of judging the walking conditions based on the measured myogenic potential.

Outline of Detailed Explanation of the Invention

This invention relates to a method for judging walking conditions using the power assisting equipment used to reduce a burden of a worker who involves in hard work. The power assisting equipment is appropriately controlled based on the result of judgment of walking conditions. ("A worker," described in the claims is defined as a person who involves in hard work in the detailed explanation of the invention. It is not supposed that the power assisting equipment of this invention assists movements of those who lost muscle strength and those who lost physical motor function for medical purposes.)

[Explanation]

The step for judging walking conditions based on the myogenic potential measured by a sensor attached to a leg part of the power assisting equipment is the step with an action by a device. Therefore, since the claimed method for judging walking conditions does not include the steps of judging for the medical purpose the physical condition of a human body such as diseases and physical health, it is not deemed as “methods of diagnosis of humans.”

According to the detailed explanation of this invention, since “a worker” is defined as a person who involves in hard work and it is not supposed that the power assisting equipment of this invention assists for the medical purpose movements of those who lost muscle strength and those who lost physical motor function, the claimed method does not fall under the method of therapy of humans.

Therefore, the claimed method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Examples 26-2 A method for controlling a power assisting device (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A method for controlling a power assisting equipment coupled to a worker to reduce his burden comprising,

a step of measuring myogenic potential of an arm or a leg of the worker by a sensor attached to the power assisting equipment, and

a step of moving the arm or the leg of the worker by driving a motor attached to the power assisting equipment based on the measured myogenic potential.

Outline of Detailed Explanation of the Invention

This invention relates to a method of appropriately controlling the power assisting equipment used to reduce a burden of a worker who involves in hard work based on the myogenic potential of an arm or a leg of the worker. ("A worker," described in the claims is defined as a person who involves in hard work in the detailed explanation of the invention. It is not supposed that the power assisting equipment of this invention assists movements of those who lost muscle strength and those who lost physical motor function for medical purposes.)

[Explanation]

This case relates to a method for controlling the power assisting equipment.

According to the detailed explanation of this invention, since “a worker” is defined as a person who involves in hard work and it is not supposed that the power assisting equipment of this invention assists for the medical purpose movements of those who lost muscle strength and those who lost physical motor function, the method for controlling the power assisting equipment of this invention does not fall under “methods of surgery, therapy or diagnosis of humans.”

Examples 26-3 A method for power assisting (An invention not considered as “methods of surgery, therapy or diagnosis of humans”)

Claim

A power assisting method to assist movements of a worker by a power assisting equipment coupled to workers to reduce their burden comprising,
a step of measuring myogenic potential of an arm or a leg of the worker by a sensor attached to the power assisting equipment, and
a step of moving the arm or the leg of the workers by driving a motor attached to the power assisting equipment based on the measured myogenic potential.

Outline of Detailed Explanation of the Invention

This invention relates to a method of appropriately controlling the power assisting equipment using judgment results of a judgment made by the power assisting equipment used to reduce a burden of a worker who involves in hard work. This invention relates to a method for controlling a power assisting equipment used to reduce a burden of a worker who involves in hard work based on the myogenic potential of an arm or an leg of the worker and assisting movements of the worker. ("A worker," described in the claims is defined as a person who involves in hard work in the detailed explanation of the invention. It is not supposed that the power assisting equipment of this invention assists movements of those who lost muscle strength and those who lost physical motor function for medical purposes.)

[Explanation]

This case relates to a power assisting method.

According to the detailed explanation of this invention, since “a worker” is defined as a person who involves in hard work and it is not supposed that the power assisting equipment of this invention assists for the medical purpose movements of those who lost muscle strength and those who lost physical motor function, the power assisting method of this invention does not fall under “methods of surgery, therapy or diagnosis of humans.”

[Reference]
The Applicable Term of These Guidelines for Industrially Applicable Inventions

The following Guidelines is only applicable to the applications filed on April 1, 1997 or later (Note)

1.1 Non-statutory Inventions (4) and (5)(b)

(As for the application filed on or before March 31, 1997, exchanged in these parts, "Examination Guidelines for Patent and Utility Model (released in June,1993) Part II: Chapter 1. Industrially Applicable Inventions," 1.1 Non-statutory Inventions (4), (5)(ii) and (iv) are applied.)

(Remark) "The applications filed on April 1, 1997 or later" includes divisional applications in accordance with Article 44 of the Patent Act whose original applications are filed on April 1, 1997 or later, converted applications in accordance with Article 46 of the Patent Act whose original applications are filed on April 1, 1997 or later, and applications claiming priority (under the Paris Convention, priority declared as governed by the Paris Convention and priority based on patent application, etc.) filed on April 1, 1997 or later.