

## **Part II: REQUIREMENTS FOR PATENTABILITY**

### **Chapter 1 Industrially Applicable Inventions**

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## **Chapter 1 Industrially Applicable Inventions**

### **The first paragraph of Section 29(1) of the Patent Law 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**

Section 2(1) of the Patent Law 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 Law, 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: Sho 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**

(1)Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body

Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body 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").

A medical device or a medicinal substances is a product, and is not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body." On the other hand, a surgical method on the human body by means of such a surgical device (e.g. scalpel) or a method for treatment of the human body with a medicinal substance is considered to be included in the category of "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

A method for controlling the operation of a medical device is not considered to be classified as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" 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. A method including an action of a medical doctor (for example, an action by a medical doctor to operate a device in order to provide medical treatment in accordance with a symptom) and/or an influence on the human body by a device (for example, the incision and/or excision of a specific part of a patient by the device) is not considered to be a method for controlling the operation of the medical device.

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 for treatment of the human body by surgery or therapy and diagnostic methods

practiced on the human body.” However, if a method for treating these samples 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 for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

A method for manufacturing a medicinal product (e.g., blood preparation, vaccine, genetically modified preparation) or 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, or the like) by utilizing raw material collected from a human being is not qualified to be placed under the category of “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”, even if the method is a method for processing the material collected from the human being based on a presupposition that the material from the human being will be returned to the same human being as part of his medical treatment.

Methods for contraception or delivery are included in “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

On the contrary, even if methods of treatment by surgery or therapy and diagnostic methods are practiced on animal bodies in general, unless it is clear that the methods of treatment are explicitly excluded from being practiced on a human body, the methods of treatment are deemed as being “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

1) Methods for treatment of the human body by surgery practiced on the human body

Methods for surgical operations and collecting blood are included in “methods for treatment of the human body by surgery practiced on the human body.” Cosmetic methods having surgical operations whose purpose is not therapeutic or diagnostic are also considered as “methods for treatment of the human body by surgery practiced on the human body.” Furthermore, preparatory treatment for surgery, such as anesthetic treatment for surgery, is also considered as methods for surgical operations because such treatment is inevitably associated with methods of surgical operations.

2) Methods for treatment of the human body by therapy practiced on the human body

These methods include the following:

- (i) methods of giving or injecting medicine or giving physical treatment to a patient for curing or restraining a disease
- (ii) methods of implanting substitute organs such as artificial internal

organs or artificial limbs

- (iii) 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.

- (iv) Methods for preparing for treatment by therapy (e.g., method for skin disinfection before giving an injection), supplemental methods for improving treatment results (e.g., rehabilitation methods), or methods for nursing associated with the treatment (e.g., methods to prevent bedsores)

### 3) Methods for treatment of the human body by diagnostic methods practiced on the human body

“Diagnostic methods practiced on the human body” include methods of gathering various kinds of data by measuring the structures or the functions of each organ in the human body for medical purposes, such as detecting diseases or recognizing or judging the physical condition of a human body, or methods of judging the condition of such human diseases.

The following are considered to be diagnostic methods practiced on the human body.

- (i) Methods of measuring the shape or size of internal organs or the conditions of the interior or exterior of the human body for the medical purposes of detecting disease or recognizing or judging the physical condition of the human body.

Example 1: A method for measuring the condition of internal organs of the human body by X-ray.

Example 2: A method for measuring the degree of skin inflammation.

- (ii) Preparatory methods for diagnosis

Example: A method for arranging electrodes for taking an electro-cardiogram.

It should be noted, however, that methods per se for measuring structures or functions of the human body for purposes other than medical ones, such as detecting diseases or recognizing or judging the physical condition of the human body, are not deemed to be “methods for the treatment of the human body by diagnostic methods.”

Example 1: A method for measuring human skin for cosmetic treatment (except for those by surgery)

Example 2: A method for measuring physical dimensions for tailoring

clothes

Example 3: A method for measuring a finger for making a ring

(Note)

A method classified as a method for controlling the operation of a medical device is not considered to be "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

## (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.

## (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**

### **Example 1 (contrary to a law of nature)**

#### **[Title of the invention]**

Method of plating copper with iron

#### **[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.

#### **[Excerpt from the detailed description 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.

## Example 2 (not utilizing a law of nature)

### [Title of the invention]

Method for calculating the sum of natural numbers  $n$  to  $n+k$

### [Claim]

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

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

### [Excerpt from the detailed description 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 (not utilizing a law of nature)**

#### **[Title of the invention]**

Method of teaching in science and mathematics courses

#### **[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.

#### **[Excerpt from the detailed description 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 (not utilizing a law of nature)

##### [Title of the invention]

Method for drawing a regular N-polygon inscribed in a given circle

##### [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;

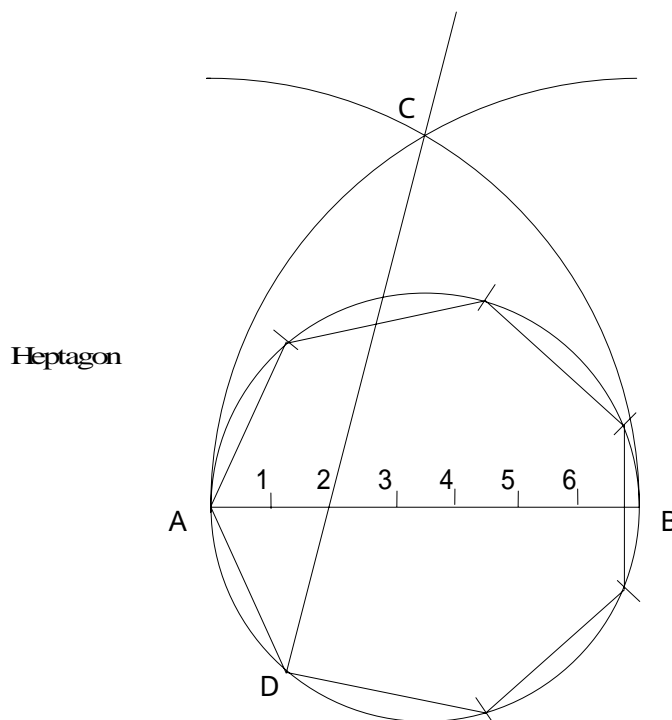
equipartitioning by a length equal to AD the circumference of the circle; and

connecting equipartitioned points on the circumference successively with linear lines to construct a regular N polygon.

##### [Excerpt from the detailed description 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 (not utilizing a law of nature)**

### **[Title of the invention]**

Method of playing a game

### **[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.

### **[Excerpt from the detailed description 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 (not utilizing a law of nature)**

### **[Title of the invention]**

Method for determining a selling price of a commodity

### **[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:

$$0 \leq f \leq 1$$

### **[Excerpt from the detailed description 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 (not utilizing a law of nature)**

### **[Title of the invention]**

Method for holding a party

### **[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.

### **[Excerpt from the detailed description 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")

**Example 8 (A method considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")**

**[Title of invention]**

Method for Gene therapy

**[Claim]**

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

**[Excerpt from the detailed description of the invention]**

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

**[Explanation]**

Methods including injection of the recombinant vector into a human body are no less than methods for treatment of the human body by therapy.

**Example 9 (A method not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body")**

**[Title of invention]**

Method for manufacturing cells for gene therapy

**[Claim]**

A method for manufacturing cells 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

**[Excerpt from detailed description of the invention]**

It was found out 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 for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" even if the cells extracted from the patient himself or herself are supposed to be used, as described in the detailed description of the invention.

**Example 10 (A method considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for giving electrical stimulus by a pacemaker

**[Claim]**

A method for giving an electrical stimulus by a pacemaker, comprising the steps of:

under control of a control means of the pacemaker,  
comparing a heart rate detected by a detecting unit with a threshold value stored in a memory device, reading out an average heart rate in a steady state from the memory device when the heart rate is lower than the threshold value, calculating the difference between the average heart rate and the detected heart rate, and setting a pulse generating the interval value in accordance with the difference, giving stimulus by a pulse generating unit to the ventricle of the heart with the pulse generating interval having been set, and keeping the heart rate steady.

**[Excerpt from the detailed description 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 performing a switching operation of the output signal.

**[Explanation]**

Since the matter reading “giving stimulus by a pulse generating unit to the ventricle of the heart with the pulse generating interval having been set, and keeping the heart rate steady” includes 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 for the treatment of the human body, 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 for the therapeutic treatment of the human body practiced on the human body as a part of the steps of the invention; thus, the method is considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**[Remark]**

It should be noted that, if the claim is amended as described in the Examples 11-13 on the basis of the description, it is not considered to be “methods

for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 11 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling a pacemaker

**[Claim]**

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

**[Excerpt from the detailed description 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 an action of a medical doctor on a human body or 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 for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”



**Example 12 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling a pacemaker

**[Claim]**

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

**[Excerpt from the detailed description 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 11, this method includes the step of generating pulses toward the outside of the pacemaker.

The matter reading “generating pulses for giving stimulus to the ventricle of the heart with the pulse generating interval set by the pulse generating means” means that “the pulse generating means” provided to 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 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 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 an action of a medical doctor and/or an influence on the human body by the device. As a result, the method is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

(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 an action of a medical doctor and/or an influence on the human body by the device.

**Example 13 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling the operation of a pacemaker

**[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, means for reading out an average heart rate at a steady state from the memory is operated when the heart rate is lower than the threshold value, 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.

**[Excerpt from the detailed description 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 to 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 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 an action of a medical doctor on the human body and/or an influence on the human body by the device. As a result, the method is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”.

**Example 14 (A method considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for giving stimulus to a retina by an artificial eye system

**[Claim]**

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

**[Excerpt from the detailed description 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 to the retina” includes 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 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.

As a result, the method in this example is considered to be a method for the treatment of the human body, 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 for treatment of the human body by therapy practiced on the human body as a part of the steps of the invention; thus, it is considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

[Remark]

It should be noted that if the claim is amended as described in Example 15 on the basis of the description, it is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 15 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling an artificial eye system

**[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 the steps of: making a picture signal by processing an outside picture image by the image receiving element of the visor device, converting the picture signal into an optical signal for transmitting to the light receiving element of the device for intraocular use from the light emitting element of the visor device, receiving the optical signal by the light receiving element of the devices for intraocular use, 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 transmitting the signal for use in the electrical stimulation to the electrode buried in the retina.

**[Excerpt from the detailed description 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 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 action of a medical doctor burying the electrode in the retina or from 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 medical device is represented as a

method and does not include an action of a medical doctor on the human body and/or an influence on the human body by the device. As a result, it is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”.

**Example 16 (A method considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for treating an affected part by micro operation robot

**[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.

**[Excerpt from the detailed description 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 action of a medical doctor viewing a monitor and operating a manipulator for treating the affected part. Furthermore, the matter reading “incising the affected part of a patient by incising means” depicts 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 for the treatment of the human body by surgery 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 for the treatment of the human body by surgery as part of the steps of the invention; thus, the method is considered to be “methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”

**[Remark]**

It should be noted that, if the claim is amended as described in Example 17 on the basis of the description, it is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the



human body.”

**Example 17 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling the operation of a micro operation robot system

**[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.

**[Excerpt from the detailed description 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 to 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 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 an action of a medical doctor on the human body and/or an influence on the human body by the device. As a result, it is not considered to be “methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**[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 an action of a medical doctor and/or 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 a medical doctor is disclosed.

**Example 18 (A method considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling an X-ray CT scanner

**[Claim]**

A method for controlling the respective parts of an X-ray CT scanner by control means, comprising the steps of:

exposing X-rays to the human body by controlling X-ray generating means, detecting the X-rays permeated through the human body by controlling X-ray detecting means, and performing reconstruction of the detected data and converting such detected data into picture data for display.

**[Excerpt from the detailed description of the invention]**

The present invention relates to a method for 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 matter reading “exposing X-rays to the human body” includes an influence on the human body by the device; thus, it is not considered to be a method for controlling the operation of the medical device.

The method in this example corresponds to a diagnostic method practiced on the human body, since it measures structures or functions of each organ in the human body for detecting diseases etc. by exposing X-rays to the human body and detecting the X-rays permeated through the human body.

Accordingly, the claimed method includes a method for treatment of the human body by therapy practiced on the human body as part of the steps of the invention; thus, it is considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**[Remark]**

It should be noted that, if the claim is amended as described in Example 19 on the basis of the description, it is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 19 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling an X-ray CT scanner

**[Claim]**

A method for controlling the respective parts of an X-ray CT scanner by control means, comprising the steps of:

generating X-rays by controlling X-ray generating means, detecting X-rays permeated through the human body by controlling X-ray detecting means, and performing reconstruction of the data detected and converting the detected data into picture data for display.

**[Excerpt from the detailed description 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 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 an action of a medical doctor or 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 an action of a medical doctor and/or an influence on the human body by the device. Accordingly, the method is not considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 20 (A method considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for Magnetic Resonance Imaging

**[Claim]**

A method for magnetic resonance imaging by a magnetic resonance imaging device comprising the steps of:  
placing a region possible of cancer in a uniform magnetic field space,  
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  $90^\circ$  pulse to the region while generating a gradient magnetic field in the slice direction, generating a predetermined quantity of the gradient magnetic field in the phase encode direction, irradiating  $180^\circ$  pulse to the region while generating the gradient magnetic field in the slice direction, and detecting a magnetic resonance signal from the pertinent region while generating the gradient magnetic field in the lead-out direction.

**[Excerpt from the detailed description 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 matter reading “placing a region possible of cancer in a uniform magnetic field space” corresponds to the action of a medical doctor in that a region possible of cancer is placed in the device.

Furthermore, the matters reading “irradiating  $90^\circ$  pulse to the region while generating a gradient magnetic field” and “irradiating  $180^\circ$  pulse to the region while generating a gradient magnetic field” include an influence on the human body by the device.

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

The claimed method corresponds to a diagnostic method practiced on a human body, since it measures the structures or functions of each organ in the human body for detecting diseases, etc., by irradiating pulses while generating a gradient magnetic field to a region possible of cancer and detecting the magnetic resonance signals.

Accordingly, the claimed method includes a method for treatment of the human body by therapy practiced on the human body as a part of the steps of the invention; thus, the method is considered to be “methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

[Remark]

It should be noted that, if the claim is amended as described in Example 21 on the basis of the description, the method is not considered to be “methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 21 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling the operation of a magnetic resonance imaging device

**[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 the 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 gradient coil generating a predetermined quantity of the gradient magnetic field in the phase encode direction, a RF coil transmitting an 180° pulse while the gradient coil is generating a gradient magnetic field in the slice direction, and 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.

**[Excerpt from the detailed description 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” belonging to 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 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 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 an action of a medical doctor and/or an influence on the human body by the device. As a result, the method is not considered to be “methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 22 (A method considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for sampling body fluid

**[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.

**[Excerpt from the detailed description 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 matter reading “the piercing element is pierced” is not a step carried out by a means provided to this fluid sampling device but by an action of a medical doctor for obtaining a sample of body fluid by using this device. (Note: In this case, the method may also be judged to include an influence on the human body via the piercing element.)

The matter reading “the body fluid is absorbed from the piercing element arranged in the vein blood vessel into the sample extracting tube” is judged to include an influence on the human body by the device, as body fluid is extracted from the human body unlike Examples 19 and 21, wherein a signal is received from the human body.

The claimed method, therefore, does not correspond to a method for controlling the operation of the medical device.

The claimed method is considered to be a diagnostic method practiced on the human body, since the method involves collecting samples from the human body for detecting disease, etc., by piercing the human body with a piercing element and sampling body fluid with an absorbing device.

Accordingly, the claimed method includes a method for diagnosing the human body as a part of the steps of the invention; thus, the method is considered to be “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

**Example 23 (A method not considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)**

**[Title of the Invention]**

Method for controlling the operation of a body fluid sampling device

**[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.

**[Excerpt from the detailed description 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 to 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 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 an action of medical doctors and/or an influence on the human body by the device. As a result, the method is not considered to be “methods for the treatment of the human body by

surgery or therapy and diagnostic methods practiced on the human body.”

**[ 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 Section 44 of the Patent Law whose original applications are filed on April 1, 1997 or later, converted applications in accordance with Section 46 of the Patent Law 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.