Appeal decision

Appeal No. 2019-40

| | |
|---|---|
| Appellant | The Hospital for Sick Children |
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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2015-562418, entitled "Methods for modulating autophagy using remote ischemic conditioning", [the international publication on Oct. 16, 2014: WO2014/167423, the national publication of the translated version on May 9, 2016: National Publication of International Patent Application No. 2016-512709] has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The present application is an application filed on Mar. 14, 2014 (priority claim under the Paris Convention, Mar. 15, 2013 US) as an international application, and the major history of the procedures after the application is shown as follows.

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| Mar. 14, 2017 | : Submission of a written amendment |
| As of Dec. 25, 2017 | : Notice of reasons for refusal |
| Jul. 9, 2018 | : Submission of a written opinion and a written amendment |
| As of Aug. 27, 2018 | : Decision of refusal |

Jan. 4, 2019 : Submission of a written request for appeal and a written amendment
Jan. 30, 2019 : Submission of a written amendment (form)
As of Apr. 15, 2019 : Reconsideration reports made to the JPO Commissioner in the procedure of reconsideration by examiners before appeal proceedings

No. 2 Decision to dismiss amendment on the amendment made on Jan. 4, 2019

[Conclusion of Decision to Dismiss Amendment]

The amendment made on Jan. 4, 2019 (hereinafter, referred to as "the Amendment") shall be dismissed.

[Reason]

1 Details of the Amendment

(1) Citations of claims after the Amendment

By the Amendment, the scope of claims was amended as follows. Note that the underlined portions are amended portions.

" [Claim 1]

A system for use in treatment of a subject having a pathological condition for which autophagy enhancement is effective, the system comprising

a device for performing remote ischemic conditioning (RIC), wherein

the treatment includes performing long-term RIC every day on the subject by the device for performing RIC, and the long-term RIC includes at least one time of RIC treatment per day, wherein

the device for performing RIC includes:

a cuff constituted so as to contract around a limb of the subject;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb; and

a controller to control the actuator in accordance with RIC treatment, wherein

the RIC treatment includes a plurality of treatment cycles, and each treatment cycle includes:

a cuff actuating phase in which the actuator makes the cuff be shrunk around the limb of the subject up to a pressure to occlude bloodstream passing through the

limb;

an ischemia duration phase in which the actuator makes, in order to occlude bloodstream passing through the limb, the cuff be maintained in a shrunken state around the limb at a set pressure;

a cuff releasing phase in which the actuator makes the cuff be released in order to enable blood to flow through the limb,

a reperfusion phase in which the cuff maintains, in order to enable blood to flow through the limb, a relaxation status around the limb, wherein,

as the subject, a subject that experiences ischemia/reperfusion injury is excluded, and wherein

execution of the long-term RIC provides enhancement of an autophagy level in the subject.

[Claim 2]

The system according to Claim 1, wherein

the pathological condition for which autophagy enhancement is effective is

(a) a neurodegenerative disease, and is optionally Alzheimer's disease, Huntington's disease, multiple sclerosis, or Parkinson's disease;

(b) a cancer, and is optionally B cell lymphoma, skin cancer, melanoma, basal cell carcinoma, liver cancer, or small cell lung cancer;

(c) an infectious disease, and is optionally Mycobacterial infection, M. tuberculosis infection, M. avium infection, M. intracellular infection, M. kansaii infection, M. gordonae infection, a Shigella flexneri infection, a Salmonella enterica infection, a Listeria monocytogenes infection, or a Francisella tularensis infection;

(d) a gastrointestinal condition, and is optionally Crohn's disease or ulcerative colitis;

(e) an autoimmune pathological condition, and is optionally rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus (SLE), lupus nephritis, ulcerative colitis, Wegener's disease, inflammatory bowel disease, idiopathic thrombocytopenic purpura (ITP), Thrombotic thrombocytopenic purpura (TTP), autoimmune thrombocytopenia, multiple sclerosis, psoriasis, IgA nephropathy, IgM polyneuropathy, myasthenia gravis, vasculitis, diabetes, Raynaud's syndrome, Schoegen's syndrome, and glomerulonephritis;

(f) a cardiovascular disease, and is optionally atherosclerosis, arteriosclerosis, cardiomyopathy, or cardiac hypertrophy;

(g) a genetic x-linked lysosome related membrane protein disease, Danone's disease, mitochondrial myopathy, or chronic myocarditis;

(h) diabetes, obesity, metabolic syndrome, glucose intolerance, hyperlipidemia, or

hypercholesterolemia; or
(i) a lung disease, and is optionally chronic obstructive pulmonary disease, cystic fibrosis, emphysema, asthma, pulmonary hypertension, or idiopathic pulmonary fibrosis.
[Claim 3]

The system according to Claim 1 or 2, wherein
the RIC treatment is performed twice or more per day.

[Claim 4]

The system according to Claim 1, wherein the RIC treatment is performed at least daily for at least one month, two months, three months, four months, five months, six months, seven months, eight months, nine months, ten months, eleven months, or a year.

[Claim 5]

The system according to Claim 1 or 2, wherein
the RIC treatment comprises
(a) two, three, four, five, or more treatment cycles, and/or
(b) a plurality of treatment cycles, each treatment cycle comprising a blood occlusion phase of five minutes and a reperfusion phase of five minutes.

[Claim 6]

The system according to Claim 1 or 2, wherein
the long-term RIC is performed repeatedly at a same site, and optionally is performed repeatedly at an upper limb or is performed repeatedly at a lower limb.

[Claim 7]

The system according to any one of Claims 1 to 6, wherein
the subject is receiving a second treatment.

[Claim 8]

The system according to Claim 7, wherein
the second treatment is applied at less than a maximal tolerated dose.

[Claim 9]

The system according to Claim 7, wherein
the second treatment is applied at more than the maximal tolerated dose.

[Claim 10]

The system according to any one of Claims 1 to 9, wherein
the subject has reduced autophagy activity."

(2) Claims before the Amendment

The citations of the scope of claims amended by the amendment made on Jul. 9, 2018 before the Amendment are as follows.

" [Claim 1]

A system for use in treatment of a subject having pathological condition or being at risk of developing pathological condition for which autophagy enhancement is effective, the system comprising

a device for performing remote ischemic conditioning (RIC), wherein

the treatment includes performing long-term RIC on the subject by the device for performing RIC, wherein

the device for performing RIC includes:

a cuff constituted so as to contract around a limb of the subject;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb; and

a controller to control the actuator in accordance with a treatment protocol, and wherein

as the subject, a subject that experiences ischemia/reperfusion injury is excluded.

[Claim 2]

The system according to Claim 1, wherein

the subject has pathological condition for which autophagy enhancement is effective.

[Claim 3]

The system according to Claim 1, wherein

the pathological condition in which autophagy enhancement is effective is

(a) neurodegenerative disease and is optionally Alzheimer's disease, Huntington's disease, multiple sclerosis, or Parkinson's disease;

(b) cancer and is optionally B cell lymphoma, skin cancer, melanoma, basal cell carcinoma, liver cancer, or small cell lung cancer;

(c) an infectious disease, and is optionally Mycobacterial infection, M. tuberculosis infection, M. avium infection, M. intracellular infection, M. kansaii infection, gordonae infection, a Shigella flexneri infection, a Salmonella enterica infection, a Listeria monocytogenes infection, or a Francisella tularensis infection;

(d) a gastrointestinal condition, and is optionally Crohn's disease or ulcerative colitis;

(e) an autoimmune pathological condition, and is optionally rheumatoid

arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus (SLE), lupus nephritis, ulcerative colitis, Wegener's disease, inflammatory bowel disease, idiopathic thrombocytopenic purpura (ITP), Thrombotic thrombocytopenic purpura (TTP), autoimmune thrombocytopenia, multiple sclerosis, psoriasis, IgA nephropathy, IgM polyneuropathy, myasthenia gravis, vasculitis, diabetes, Raynaud's syndrome, Schoegen's syndrome, and glomerulonephritis;

(f) a cardiovascular disease, and is optionally atherosclerosis, arteriosclerosis, cardiomyopathy, or cardiac hypertrophy;

(g) a genetic x-linked lysosome related membrane protein disease, Danone's disease, mitochondrial myopathy, or chronic myocarditis;

(h) diabetes, obesity, metabolic syndrome, glucose intolerance, hyperlipidemia, or hypercholesterolemia; or

(i) a lung disease, and is optionally chronic obstructive pulmonary disease, cystic fibrosis, emphysema, asthma, pulmonary hypertension, or idiopathic pulmonary fibrosis.

[Claim 4]

The system according to any one of Claims 1 to 3, wherein

RIC is performed

(a) every day, and/or

(b) twice or more per day.

[Claim 5]

The system according to any one of Claims 1 to 3, wherein

RIC is performed

(a) at least daily for at least one month, two months, three months, four months, five months, six months, seven months, eight months, nine months, ten months, eleven months, or a year, or

(b) every other day for at least one month, two months, three months, four months, five months, six months, seven months, eight months, nine months, ten months, eleven months, or a year.

[Claim 6]

The system according to any one of Claims 1 to 3, wherein

RIC comprises

(a) one, two, three, four, five or more cycles, each cycle comprising a blood occlusion phase and a reperfusion phase, and/or

(b) one or more cycles, each cycle comprising a blood occlusion phase of five minutes and a reperfusion phase of five minutes.

[Claim 7]

The system according to any one of Claims 1 to 3, wherein

RIC is performed repeatedly at a same site, and optionally is performed repeatedly at an upper limb or is performed repeatedly at a lower limb.

[Claim 8]

The system according to any one of Claims 1 to 7, wherein

the subject is receiving a second treatment.

[Claim 9]

The system according to Claim 8, wherein

the second treatment is applied at less than a maximal tolerated dose.

[Claim 10]

The system according to Claim 8, wherein

the second treatment is applied at more than the maximal tolerated dose.

[Claim 11]

The system according to any one of Claims 1 to 10, wherein

the subject has reduced autophagy activity."

2 Amended matters by the Amendment

As viewed from the above-mentioned 1, the amended matters by the Amendment are the following (2-1) to (2-15).

(2-1) "A subject having pathological condition or being at risk of developing a pathological condition for which autophagy enhancement is effective" recited in Claim 1 before amendment is amended to "a subject having a pathological condition for which autophagy enhancement is effective".

(2-2) "Performing long-term RIC" recited in Claim 1 before amendment is amended to "performing long-term RIC every day".

(2-3) It is specified that "long-term RIC" recited in Claim 1 before amendment includes "at least one time of RIC treatment per day".

(2-4) "A controller to control the actuator in accordance with a treatment protocol" recited in Claim 1 before amendment is amended to "a controller to control the actuator in accordance with RIC treatment", and, in addition, it is specified that

the RIC treatment includes

"a plurality of treatment cycles, and each treatment cycle includes:

a cuff actuating phase in which the actuator makes the cuff be shrunk around the limb of the subject up to a pressure to occlude bloodstream passing through the limb;

an ischemia duration phase in which the actuator makes, in order to occlude bloodstream passing through the limb, the cuff be maintained in a shrunken state around the limb at a set pressure;

a cuff releasing phase in which the actuator makes the cuff be released in order to enable blood to flow through the limb,

a reperfusion phase in which the cuff maintains, in order to enable blood to flow through the limb, a relaxation status around the limb,".

(2-5) Regarding "long-term RIC" recited in Claim 1 before amendment, it is specified that

"execution of the long-term RIC provides enhancement of an autophagy level in the subject".

(2-6) Along with the above-mentioned (2-1), Claim 2 before amendment is deleted.

(2-7) Along with the above-mentioned (2-6), the item number of Claim 3 before amendment is advanced to claim 2, and the claim which it refers to is amended from "Claim 1 or 2" to "Claim 1".

(2-8) Along with the above-mentioned (2-6), the item number of Claim 4 before amendment is advanced to Claim 3, and, in addition, the claim it refers to is amended from "any one of Claims 1 to 3" to "Claim 1"; "RIC" is amended to "RIC treatment", and, further, "is performed (a) every day, and/or (b) twice or more per day" is amended to "is performed twice or more per day".

(2-9) Along with the above-mentioned (2-6), the item number of Claim 5 before amendment is advanced to Claim 4, and, in addition, the claim it refers to is amended from "any one of Claims 1 to 3" to "Claim 1"; "RIC" is amended to "RIC treatment", and, further,

"is performed

(a) at least daily for at least one month, two months, three months, four

months, five months, six months, seven months, eight months, nine months, ten months, eleven months, or a year, or

(b) every other day for at least one month, two months, three months, four months, five months, six months, seven months, eight months, nine months, ten months, eleven months, or a year" is amended to

"is performed at least daily for at least one month, two months, three months, four months, five months, six months, seven months, eight months, nine months, ten months, eleven months, or a year".

(2-10) Along with the above-mentioned (2-6), the item number of Claim 6 before amendment is advanced to Claim 5, and, together with this, the claim it refers to is amended from "any one of Claims 1 to 3" to "Claim 1 or 2"; "RIC" is amended to "RIC treatment", "one, two, three, four, five cycles" is amended to "two, three, four, five treatment cycles"; and, further, "comprises one or more cycles, each cycle" is amended to "comprises a plurality of treatment cycles, each treatment cycle".

(2-11) Along with the above-mentioned (2-6), the item number of Claim 7 before amendment is advanced to Claim 6, and, together with this, the claim it refers to is amended from "any one of Claims 1 to 3" to "Claim 1 or 2".

(2-12) Along with the above-mentioned (2-6), the item number of Claim 8 before amendment is advanced to Claim 7, and, together with this, the claim it refers to is amended from "any one of Claims 1 to 7" to "any one of Claims 1 to 6".

(2-13) Along with the above-mentioned (2-6), the item number of Claim 9 before amendment is advanced to Claim 8, and, together with this, the claim it refers to is amended from "Claim 8" to "Claim 7".

(2-14) Along with the above-mentioned (2-6), the item number of Claim 10 before amendment is advanced to Claim 9, and, together with this, the claim it refers to is amended from "Claim 8" to "Claim 7".

(2-15) Along with the above-mentioned (2-6), the item number of Claim 11 before amendment is advanced to Claim 10, and, together with this, the claim it refers to is amended from "any one of Claims 1 to 10" to "any one of Claims 1 to 9".

3 Propriety of the amendment

The Amended matter (2-6) falls under the category of ones for the purpose of cancellation of claims of Article 17-2(5)(i) of the Patent Act.

The Amended matter (2-1) is one that restricts a subject on which the system is applied, the Amended matters (2-2)-(2-5) are ones that restrict the contents of "long-term RIC", the Amended matters (2-7), (2-8) and (2-11)-(2-15) are ones that make, along with the Amended matter (2-6), the claim numbers of Claims 3, 4, 7-11 before amendment be advanced, and, together with this, the number of claims that each of these refers to be reduced, and the Amended matters (2-9) and (2-10) are ones that make, along with the Amended matter (2-6), the claim numbers of Claims 5 and 6 before amendment be advanced, and, in conjunction with this, the number of claims that each of these refers to be reduced, and, further, are ones that restrict the contents of "RIC"; the field of industrial application and the problem to be solved are identical between the inventions recited in Claims 1 and 3-11 before amendment and the inventions recited in Claims 1 to 10 after amendment; and, therefore, these fall under the category of ones for the purpose of "restriction of the scope of claims" of Article 17-2(5)(ii) of the Patent Act.

Therefore, whether the invention according to Claim 1 (hereinafter, referred to as "The Amended Invention") among Claims 1 to 10 of the scope of claims after the Amendment complies with the provision of Article 126(7) of the Patent Act as applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the same Act (that is, whether it is one for which the Appellant can be granted a patent independently at the time of filing of the patent application) will be examined, hereinafter.

(1) The Amended Invention

The Amended Invention is one recited in Claim 1 of the scope of claims that was amended by the Amendment described in the above-mentioned "1(1)" as follows.
" [Claim 1]

A system for use in treatment of a subject having a pathological condition for which autophagy enhancement is effective, the system comprising

a device for performing remote ischemic conditioning (RIC), wherein

the treatment includes performing long-term RIC every day on the subject by the device for performing RIC, and the long-term RIC includes at least one time of RIC treatment per day, wherein

the device for performing RIC includes:

a cuff constituted so as to contract around a limb of the subject;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb; and

a controller to control the actuator in accordance with RIC treatment, wherein

the RIC treatment includes a plurality of treatment cycles, and each treatment cycle includes:

a cuff actuating phase in which the actuator makes the cuff be shrunk around the limb of the subject up to a pressure to occlude bloodstream passing through the limb;

an ischemia duration phase in which the actuator makes, in order to occlude bloodstream passing through the limb, the cuff be maintained in a shrunken state around the limb at a set pressure;

a cuff releasing phase in which the actuator makes the cuff be released in order to enable blood to flow through the limb,

a reperfusion phase in which the cuff maintains, in order to enable blood to flow through the limb, a relaxation status around the limb, wherein,

as the subject, a subject that experiences ischemia/reperfusion injury is excluded, and wherein

execution of the long-term RIC provides enhancement of an autophagy level in the subject."

(2) Matters described in Cited Document 1, and the Cited Invention (the invention described in Cited Document 1)

A In Cited Document 1 (National Publication of International Patent Application No. 2010-512176) cited in the reasons for refusal stated in the examiner's decision, there are described the following matters.

Described matter (1a)

"[Claim 1]

A system for remote preconditioning, comprising:

a cuff configured to contract around a limb of an examinee;

an actuator connected to the cuff so as to cause the cuff to contract around the limb of the examinee during operation to reduce a blood flow of the limb; and

a controller for controlling the actuator according to a treatment protocol

including a plurality of treatment cycles, wherein each of the treatment cycles includes:

cuff actuation in which the actuator causes the cuff around the limb of the examinee to contract to a pressure above a systolic pressure to occlude the blood flow of the limb;

an ischemic period in which the actuator maintains the cuff around the limb at a set value higher than the systolic pressure to occlude the blood flow of the limb and continues the maintained state for at least five seconds;

pressure releasing in which the actuator releases the cuff to allow the blood flow of the limb; and

a reperfusion period in which the cuff is held around the limb in a relaxed state to allow the blood flow of the limb, and that lasts one minute or more.

... Omitted ...

[Claim 18]

The system according to Claim 1, wherein

the treatment cycle is repeated five times during the treatment protocol."

([Claim 1] - [Claim 18])

Described matter (1b)

"[0001]

The present invention relates to a system for performing remote preconditioning.

[Background Art]

[0002]

Ischemic diseases are a major cause of mortality in industrialized countries. Tissue damage has been confirmed to be due to ischemia (cessation of blood flow to tissue) and associated reperfusion (re-entry of blood into tissue). Ischemia and reperfusion disturb microcirculation and leads to tissue damage and organ dysfunction.

[0003]

It is known that, in ischemic preconditioning (IPC), a portion of the body of an examinee is made to be in a state of ischemic onset for a short period of time, which causes the tissue to resist injury in subsequent ischemic onsets. Such phenomenon of ischemic preconditioning is first described by Murry et al. and has been demonstrated in most mammalian tissues. At the moment, IPC is recognized as one of the most effective innate protective mechanisms for ischemic reperfusion (I-R) injury. It is possible to demonstrate a robust protective efficacy by experimental models, but there

are only a relatively small number of clinical reports regarding its effectiveness. This is at least partially related to the difficulty of temporarily causing ischemia of the target organ prior to therapeutic intervention. Also, the method of inducing IPC itself may lead to tissue dysfunction." ([0001] - [0003])

Described matter (1c)
"[0004]

Remote preconditioning (rIPC) refers to purposefully inducing a temporary ischemia at a location away from at least some of the tissues to be protected of an examinee. A rIPC often causes a temporary ischemia of a limb to protect an organ located away from the limb of the examinee. Remote preconditioning (rIPC) was first described by Przyklenk et al. in 1993. It was found by Przyklenk et al. that, by means of a temporary ischemia in the region of the coronary circumflex artery, it is ensured that the myocardium at a distant location is resistant to injury and that ischemia of the left anterior coronary region is prolonged. Myocardial protection has been demonstrated by various remote stimuli, including renal ischemia, liver ischemia, ischemia of the mesenteric artery, and ischemia of skeletal muscle hindlimbs.
[0005]

Remote preconditioning has been performed using a blood pressure monitor (sphygnamometer), which is generally an instrument used to measure the blood pressure of an examinee. The cuff of the sphygmomanometer is wrapped around an arm of an examinee and inflated to a pressure sufficient to occlude the blood flow of the arm (i.e., a pressure above the examinee's systolic pressure). The blood pressure monitor is maintained in an inflated state so as to stop the blood flow in the limb for a period defined by the physician (referred to herein as an ischemic period). After the ischemic period, pressure is released from the cuff and the blood flow of the limb is reperfused for a given period of time (referred to herein as a reperfusion period). Thereafter, the blood pressure monitor is again inflated and these steps are repeated the number of times which is determined by the physician." ([0004] - [0005])

Described matter (1d)
"[0012]

According to one aspect of the present invention, a system for performing remote preconditioning is disclosed. The system includes a cuff configured to contract around a limb of an examinee. An actuator is connected to the cuff. The actuator causes the cuff to contract around the limb of the examinee in operation to reduce the

blood flow of the limb. Control of the actuator is performed by a controller according to a treatment protocol including a plurality of treatment cycles. Each treatment cycle includes cuff actuation and an ischemic period. During the cuff actuation, the actuator constricts the cuff around the examinee's limb until a pressure above the systolic pressure is reached to occlude the blood flow of the limb. During the ischemic period, the actuation actuator maintains the cuff around the limb at a set value above the systolic pressure so as to occlude the blood flow of the foot. The ischemic period lasts for at least five seconds. Each treatment cycle includes pressure releasing in which the cuff is released by the actuator to allow the blood flow through the limb, and a reperfusion period in which the cuff is maintained in a relaxed state around the limb to allow the blood flow of the foot. The reperfusion period lasts for at least one minute." ([0012])

Described matter (1e)

"[FIG. 1] FIG. 1 is a schematic diagram of an embodiment of a remote preconditioning system including an inflatable cuff configured to contract around a limb of an examinee.

[0017]

The overall system illustrated in FIG. 1 includes a cuff 10, an actuator 12, a controller 14, and a user interface 16. The cuff is configured to be wound on an examinee's limb 15, e.g., on an arm or leg of the examinee. The actuator causes the cuff to contract around the limb when actuated to occlude the blood flow of the limb. The controller performs a treatment protocol that repeats one or multiple treatment cycles. The treatment cycle itself includes the steps of actuating a cuff to inhibit a blood flow, maintaining the cuff in an actuated state during an ischemic period, releasing the cuff, and maintaining the cuff in a relaxed state to perform reperfusion.

【図１】

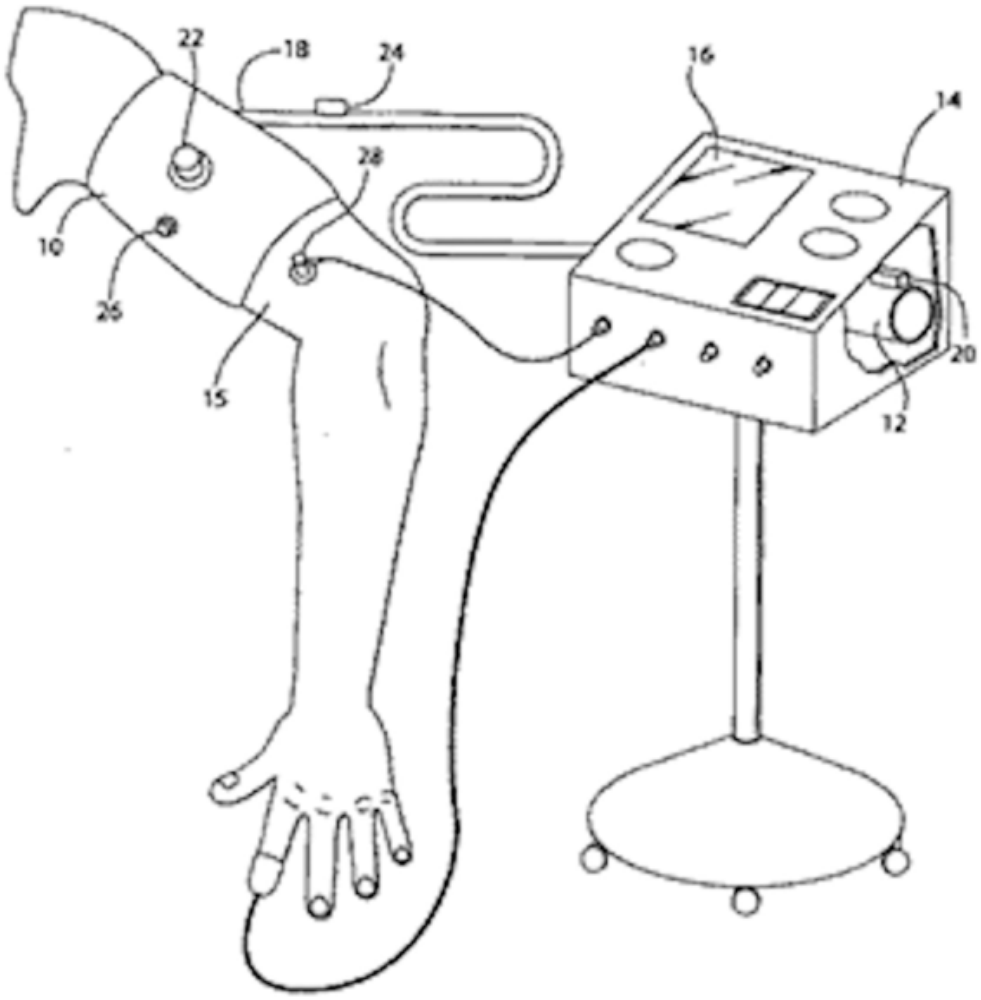



Fig. 1

" (The simple description of [FIG. 1] in [0014], and [0017] and [FIG. 1])

Described matter (1f)

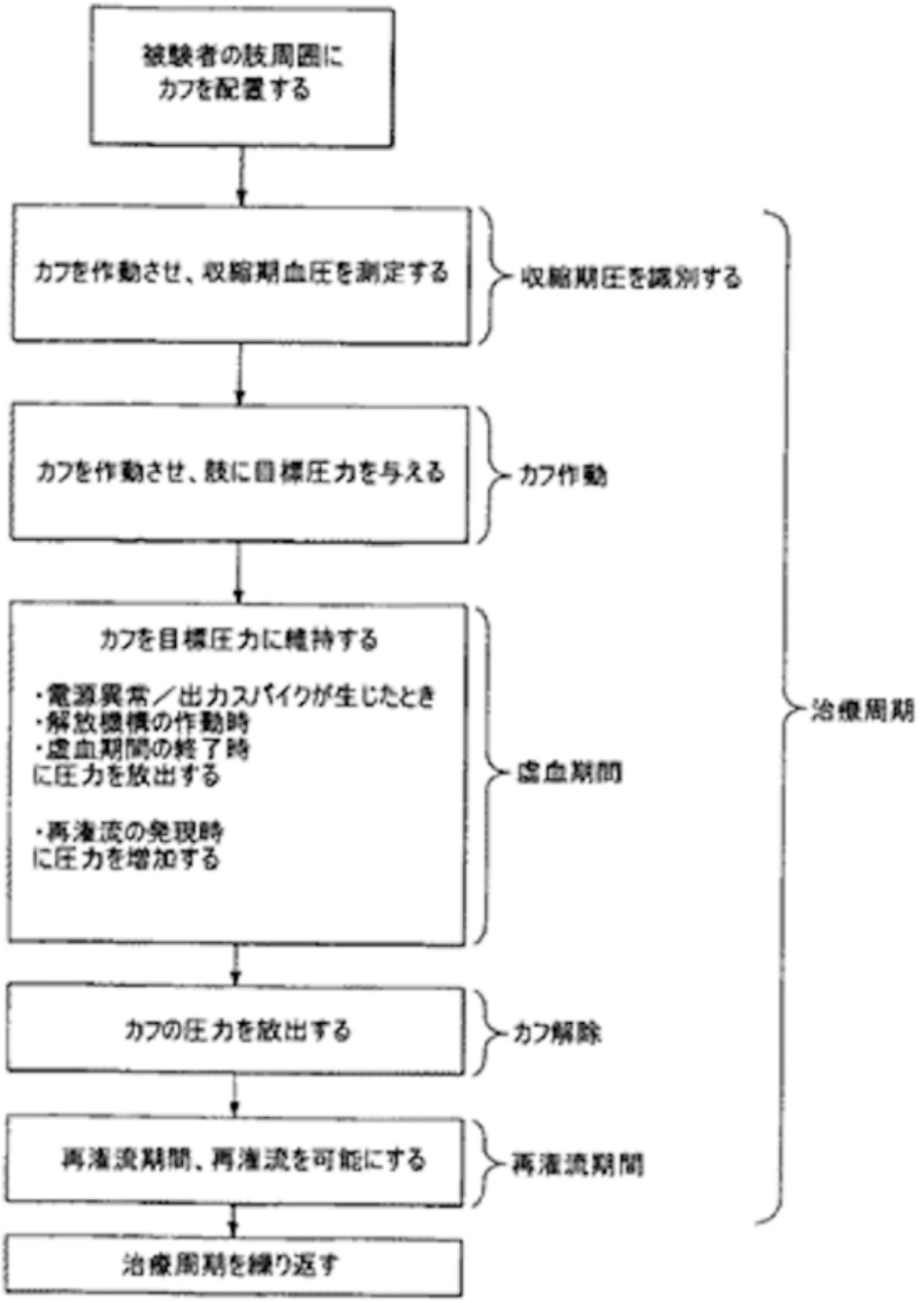
"[FIG. 2] A block diagram showing one embodiment of the operation scheme of an rIPC system.

[0018]

FIG. 2 is a block diagram illustrating an operation scheme used to perform rIPC according to an embodiment of the present invention. In this scheme, a cuff is first wound on an examinee's limb. The system then operates and initiates a treatment

protocol via the controller. In one embodiment, activation of the system is performed by a medical professional. In other embodiments, activation of the system may be performed by the examinee itself. Deflation of the cuff imparts an initial pressure above the systolic pressure to the examinee's limb. As used herein, the initial pressure may be a default value of the system. Alternatively, the initial pressure may be programmed into a particular treatment protocol. By monitoring the appearance of Korotkoff sound or vibration as a result of deflation of the cuff, the examinee's systolic pressure is identified. Once the systolic pressure is identified, the system begins the first treatment cycle of the treatment protocol. In some embodiments, the systolic pressure may be identified as the first portion of the treatment protocol.

【図２】




【図２】 [FIG. 2]

被験者の肢周囲にカフを配置する Arrange cuff around examinee's limb

カフを作動させ、収縮期血圧を測定する Actuate cuff to measure systolic blood pressure

| | |
|---|---|
| 収縮期圧を識別する | Identify systolic pressure |
| カフを作動させ、肢に目標圧力を与える | Actuate cuff to give target pressure to limb |
| カフ作動 | Cuff actuation |
| カフを目標圧力に維持する | Maintain cuff at target pressure |
| ・電源異常／出力スパイクが生じたとき | · When power abnormality/output spike is caused |
| ・解放機構の作動時 | · At the time of operation of release mechanism |
| ・虚血期間の終了時 | · At the time of end of ischemic period |
| に圧力を放出する | Release pressure |
| ・再灌流の発現時 | · On the occasion of appearance of reperfusion |
| に圧力を増加する | Increase pressure |
| 虚血期間 | Ischemic period |
| カフの圧力を放出する | Release cuff pressure |
| カフ解除 | Cuff releasing |
| 再灌流期間、再灌流を可能にする | Enable reperfusion during reperfusion period, |
| 再灌流期間 | Reperfusion period |
| 治療周期を繰り返す | Repeat treatment cycle |
| 治療周期 | Treatment cycle |

" (simple description of [FIG. 2] in [0014], and [0018] and [FIG. 2])

Described matter (1g)

"[0019]

When the cuff contracts and a target pressure that is higher than the examinee's systolic pressure by an amount defined in the treatment protocol is applied to the examinee's limb, the treatment cycle begins. This occludes a blood flow in the examinee's limb. External pressure on the limb of the examinee is maintained for an ischemic period defined in the treatment protocol. The system monitors the examinee for the ischemic period regarding the pressure release criteria (e.g., power failure of the system, power spike of the system, and manual actuation of the quick release mechanism). The system also monitors the examinee for the ischemic period regarding an indication of reperfusion of the examinee's limb. Then, to prevent

reperfusion, the external pressure provided by the cuff is increased. The indication of reperfusion includes the onset of Korotkoff sound or vibration. After the ischemic period, the cuff releases the pressure around the examinee's limb and allows reperfusion. Reperfusion may be performed for a reperfusion period defined in the treatment cycle." ([0019])

Described matter (1h)
"[0035]

As described above, the system includes a treatment protocol that directs operation of the system via a controller. Embodiments of the treatment protocol include a treatment cycle including cuff actuation, an ischemic period, cuff releasing, and a reperfusion period. In many embodiments of the treatment protocol, the treatment cycle may be repeated multiple times. Also, some embodiments of the treatment protocol include an identification of a systolic pressure.
[0036]

The cuff-actuation part of the treatment cycle includes contracting the cuff around the examinee's limb to occlude the blood flow of the limb. The contraction of the cuff is performed by reading an indication (e.g., a set value that becomes a target pressure of the cuff) from the treatment protocol by the controller and initializing the controller so that the cuff reaches the target set value. Whether the target set value has been reached may be sensed using the sensors and techniques described herein.
[0037]

During the ischemic phase of the treatment cycle, pressure is maintained around the limb so that the blood flow of the examinee's limb does not reperfuse. The length of an ischemic phase (referred to as an ischemic period) is generally determined by a physician or another medical professional, and programmed into the treatment protocol. The ischemic period may be a few seconds, or as much as 20 minutes, or a period longer than that, but the embodiments of the invention are not limited thereto. In some embodiments, the ischemic period varies for each treatment cycle in the same treatment protocol, but in other embodiments it is constant.
[0038]

The controller operates to maintain the pressure provided by the cuff at a set value higher than the examinee's systolic pressure. In an embodiment of a cuff, the cuff may be gradually relaxed from an examinee's limb to reduce pressure and consequently allow reperfusion. This is caused by a variety of factors such as relaxation of the muscles of the limb of the examinee, stretching of the cuff around the

limb, and (intentional or unintentional) air leakage. To this end, the sensor may provide a pressure reading as feedback to the controller. The controller may measure a difference between the set value and the read actual pressure value and may send a required command to the actuator to compensate for the error.
[0039]

Various methods may be used to appropriately define the set value of the controller during an ischemic period. According to one embodiment, the set value is manually entered into a treatment protocol by a physician (or another medical professional). Alternatively, the set value may be selected by a physician in view of the examinee's systolic pressure.... Omitted from the last part ...." ([0035] - [0039])

Described matter (1i)
"[0044]

In an embodiment of the treatment cycle, the reperfusion period is next to cuff releasing. The reperfusion of a limb may be performed for a constant period of time (which is referred to as a reperfusion period). As with the ischemic period, the length of reperfusion may vary, such as five seconds, one minutes, 20 minutes, or longer. The reperfusion period may be constant for each treatment cycle if the treatment protocol is common. Embodiments of the present invention are not limited to this, and the reperfusion period may be different in each treatment cycle.
[0045]

The treatment cycles of the treatment protocol may be any number of times. As described herein, a common treatment cycle may simply be repeated two, three, four or more times, until completion of the treatment protocol. Alternatively, the treatment cycles of the treatment protocol may be programmed with different parameters. Different parameters may be, for example, a different ischemia period, a reperfusion period, a set value of pressure during an ischemic period, etc." ([0044] - [0045])

B The invention described in Cited Document 1 (Cited Invention)

Regarding background of the invention of the system for performing remote preconditioning described in Cited Document 1 (Described matter (1a)), it is described in Cited Document 1 that: in ischemia preconditioning (IPC), by making a part of the body of an examinee be in a state of ischemia onset for a short time, the tissue becomes resistant to injury in subsequent ischemic onsets (Described matter (1b)); remote preconditioning (rIPC) means purposefully inducing a temporary ischemia at a location

away from at least some of the tissues to be protected of an examinee, and often causes a temporary ischemia of a limb to protect an organ located away from the limb of the examinee; and, in remote preconditioning, the cuff of a blood pressure monitor (sphygnamometer) is wrapped around an arm of an examinee and inflated to a pressure sufficient to occlude the blood flow of the arm (i.e., a pressure above the examinee's systolic pressure), the blood pressure monitor is maintained in an inflated state so as to stop the blood flow in the limb for a period defined by the physician (an ischemic period), after the ischemic period, pressure is released from the cuff and the blood flow of the limb is reperfused for a given period of time (a reperfusion period), and, thereafter, the blood pressure monitor is again inflated, and these steps are repeated the number of times which is determined by the physician (Described matter (1c)).

According to these descriptions, it can be said that, generally, a system for performing remote preconditioning (rIPC) is a system for performing treatment of an examinee so as to make tissues to be protected become resistant to injury, by repeating a step of, after purposefully inducing a temporary ischemia at a location away from at least some of the tissues to be protected of an examinee for a period defined by the physician (an ischemic period), causing reperfusion of the limb blood for a given period (reperfusion period) the number of times determined by the physician in a rapid manner.

Then, the system for performing remote preconditioning recited in the scope of claims of Cited Document 1 (Described matter (1a)) is a system including a device including a cuff, an actuator and a controller shown in [FIG. 1] (Described matter (1d) and (1e)), and the operation scheme of the relevant device is, as expressed in [FIG. 2], an operation scheme to perform remote preconditioning in which, after arranging a cuff around an examinee's limb, a treatment cycle including cuff actuation of giving a target pressure to the limb, an ischemic period to maintain the cuff at the target pressure, cuff releasing to release the pressure of the cuff, and a reperfusion period to enable reperfusion is repeated (Described matter (1f) to (1i)).

From these descriptions, in Cited Document 1, it can be said that it is described that the above-mentioned device is a device for performing remote preconditioning, and there is described a system for use in treatment of an examinee including performing remote preconditioning on the examinee by the above-mentioned device.

Then, it is recognized that, in Cited Document 1, there is described the following invention (hereinafter, referred to as "Cited Invention")

"A system for use in treatment of an examinee comprising

a device for performing remote preconditioning, wherein

the treatment includes performing remote preconditioning on the examinee by the device,

the device for performing remote preconditioning includes:

a cuff configured to contract around a limb of the examinee;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the examinee to reduce bloodstream passing through the limb; and

a controller for controlling the actuator according to a treatment protocol including a plurality of treatment cycles, wherein each of the treatment cycles includes:

cuff actuation in which the actuator causes the cuff around the limb of the examinee to contract to a pressure above a systolic pressure to occlude the blood flow of the limb;

an ischemic period in which the actuator maintains the cuff around the limb at a set value higher than the systolic pressure to occlude the blood flow of the limb and continues the maintained state for at least five seconds;

pressure releasing in which the actuator releases the cuff to allow the blood flow of the limb; and

a reperfusion period in which the cuff is held around the limb in a relaxed state to allow the blood flow of the limb, and that lasts at least one minute."

(3) Comparison between the Amended Invention and Cited Invention, and judgment

A "Remote ischemic conditioning (RIC)" in the Amended Invention means "a non-invasive process to purposefully induce induction of an ischemic event or duration of ischemia (typically, due to occlusion of an artery bloodstream) and a subsequent reperfusion event or duration of reperfusion (typically when reperfusion of blood is allowed), and this non-invasive process is performed typically at an upper limb or lower limb, or at an area of a body distant from organs or tissues for which the process itself is intended to be effective" ([0035] of the description of the present application).

Then, "remote preconditioning" in Cited Invention is one that "purposefully induces a temporary ischemia at a location away from at least some of the tissues to be protected of a subject" (Described matter (1c), and, further, is one in which, as shown in [FIG. 2], a reperfusion period to enable reperfusion is induced by cuff releasing after the ischemic period (Described matter (1f) to (1i)), and, therefore, "remote preconditioning" in Cited Invention corresponds to "remote ischemic conditioning (RIC)" in the Amended Invention.

In addition, "examinee" in Cited Invention corresponds to "subject" in the

Amended Invention.

B Regarding "a device for performing remote ischemic conditioning (RIC)" in the Amended Invention, there are the following descriptions in the description of the present application.

"[0035]

Remote ischemic conditioning (RIC)

Remote ischemic conditioning (RIC), as used herein, means a non-invasive process to purposefully induce induction of an ischemic event or duration of ischemia (typically, due to occlusion of an artery bloodstream) and a subsequent reperfusion event or duration of reperfusion (typically when reperfusion of blood is allowed), and this non-invasive process is performed typically at an upper limb or lower limb, or at an area of a body distant from organs or tissues for which the process itself is intended to be effective.

...

[0040]

Devices for performing RIC are known in the art and include those described in the description of U.S. Pat. No. 7717855 and the description of U.S. Patent Application Publication No. 2012/0265240A1 (both of which are incorporated herein by reference in their entirety). Briefly, this system includes a cuff configured to contract around a subject's limb, an actuator coupled to the cuff for, when in operation, contracting the cuff around the subject's limb to reduce a blood flow therethrough, and a controller to control the actuator in accordance with a treatment protocol. The treatment protocol typically includes a plurality of treatment cycles, and each of the treatment cycles may include: a cuff actuating phase in which the actuator contracts the cuff around the subject's limb to a pressure to occlude bloodstream passing through the limb; an ischemia duration phase in which the actuator maintains the cuff around the limb at a set pressure point in a contracted state to occlude the bloodstream passing through the limb; and a reperfusion phase in which the cuff is maintained in a relaxed state around the limb to enable bloodstream to flow." ([0035] - [0040])

Then, regarding "a device for performing remote preconditioning" of Cited Invention, there are the following descriptions in Cited Document 1.

"[0004]

Remote preconditioning (rIPC) means purposefully inducing a temporary ischemia at a location away from at least some of the tissues to be protected of a subject. The rIPC often causes a temporary ischemia of a limb to protect an organ located away

from the limb of the examinee. ... Omitted ....
[0005]

Remote preconditioning (rIPC) has been performed using a blood pressure monitor (sphygnamometer), which is generally an instrument used to measure the blood pressure of an examinee. The cuff of the sphygmomanometer is wrapped around an arm of an examinee and inflated to a pressure sufficient to occlude the blood flow of the arm (i.e., a pressure above the examinee's systolic pressure). The blood pressure monitor is maintained in an inflated state so as to stop blood flow in the limb for a period defined by the physician (referred to herein as an ischemic period). After the ischemic period, pressure is released from the cuff and the blood flow of the limb is reperfused for a given period of time (referred to herein as a reperfusion period). Thereafter, the blood pressure monitor is again inflated and these steps are repeated the number of times which is determined by the physician." ([0004] - [0005] of Described matter (1c))

"[0012]

According to one aspect of the invention, a system for performing remote preconditioning is disclosed. The system includes a cuff configured to contract around a limb of an examinee. An actuator is connected to the cuff. The actuator causes the cuff to contract around the limb of the examinee in operation to reduce the blood flow of the limb. Control of the actuator is performed by a controller according to a treatment protocol including a plurality of treatment cycles. Each treatment cycle includes cuff actuation and an ischemic period. During the cuff actuation, the actuator constricts the cuff around the examinee's limb until a pressure above the systolic pressure is reached to occlude the blood flow of the limb. During the ischemic period, the actuation actuator maintains the cuff around the limb at a set value above the systolic pressure so as to occlude the blood flow of the foot. The ischemic period lasts for at least five seconds. Each treatment cycle includes pressure releasing in which the cuff is released by the actuator to allow the blood flow through the limb, and a reperfusion period in which the cuff is maintained in a relaxed state around the limb to allow the blood flow of the foot. The reperfusion period lasts for at least one minute." (Description (1d))

C In view of the descriptions of the present application and Cited Document 1 indicated in the above B, and Described matter (1f)-(1i), "a cuff configured to contract around a limb of the examinee", "an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the examinee to reduce bloodstream passing

through the limb", and "a controller for controlling the actuator according to a treatment protocol including a plurality of treatment cycles" in Cited Invention respectively correspond to "a cuff constituted so as to contract around a limb of the subject", "an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb", and "a controller to control the actuator in accordance with RIC treatment" in the Amended Invention.

Then, "cuff actuation in which the actuator causes the cuff around the limb of the examinee to contract to a pressure above a systolic pressure to occlude the blood flow of the limb", "an ischemic period in which the actuator maintains the cuff around the limb at a set value higher than the systolic pressure to occlude the blood flow of the limb and continues the maintained state for at least five seconds", "pressure releasing in which the actuator releases the cuff to allow the blood flow of the limb", and "a reperfusion period in which the cuff is held around the limb in a relaxed state to allow the blood flow of the limb, and that lasts at least one minute" in Cited Invention respectively correspond to "a cuff actuating phase in which the actuator makes the cuff be shrunk around the limb of the subject up to a pressure to occlude bloodstream passing through the limb", "an ischemia duration phase in which the actuator makes, in order to occlude bloodstream passing through the limb, the cuff be maintained in a shrunk state around the limb at a set pressure", "a cuff releasing phase in which the actuator makes the cuff be released in order to enable blood to flow through the limb", and "a reperfusion phase in which the cuff maintains, in order to enable blood to flow through the limb, a relaxation status around the limb" in the Amended Invention.

In addition, in Cited Document 1, it is described in [FIG. 2] showing the operation scheme of the device in Cited Invention (Described matter (1f)) that "treatment cycle is repeated", and, therefore, treatment in Cited Invention corresponds to "RIC treatment" including "a plurality of treatment cycles" of the Amended Invention.

D From the above A to C, the Amended Invention and Cited Invention are identical in a point of being an invention as

"A system for use in treatment of a subject, the system comprising

a device for performing remote ischemic conditioning (RIC), wherein

the device for performing RIC includes:

a cuff constituted so as to contract around a limb of the subject;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb; and

a controller to control the actuator in accordance with RIC treatment, wherein

the RIC treatment includes a plurality of treatment cycles, and each treatment cycle includes:

a cuff actuating phase in which the actuator makes the cuff be shrunk around the limb of the subject up to a pressure to occlude bloodstream passing through the limb;

an ischemia duration phase in which the actuator makes, in order to occlude bloodstream passing through the limb, the cuff be maintained in a shrunken state around the limb at a set pressure;

a cuff releasing phase in which the actuator makes the cuff be released in order to enable blood to flow through the limb,

a reperfusion phase in which the cuff maintains, in order to enable blood to flow through the limb, a relaxation status around the limb.", and are different in the following points although not quite satisfactorily.

(Different Feature 1) In the Amended Invention, "subject" is a "subject having a pathological condition for which autophagy enhancement is effective", and "as the subject, a subject that experiences ischemia/reperfusion injury is excluded" is specified, whereas, in Cited Invention, "subject" is not specified as such.
(Different Feature 2) In the Amended Invention, "treatment" "includes performing long-term RIC every day on the subject by the device for performing RIC, and the long-term RIC includes at least one time of RIC treatment per day", and "execution of the long-term RIC provides enhancement of an autophagy level in the subject" is specified, whereas, in Cited Invention, "treatment" is not specified as including such long-term RIC.

E The above-mentioned different features are examined.

Both of the Amended Invention and Cited Invention are inventions of a "system for use in treatment of a subject" including a "device for performing remote ischemic conditioning (RIC)" including a "cuff" for obtaining the cuff actuating phase and the reperfusion phase, an "actuator" for obtaining the ischemia duration phase and the cuff releasing phase, and a "controller" for controlling the actuator, as instructed in the above D.

Both of the matter that specifies "subject" (the above-mentioned (Different Feature 1)) and the matter that specifies "treatment" (the above-mentioned (Different Feature 2)) in the Amended Invention are matters that specify a method for using the system of the Amended Invention, and are not matters that specify a shape, a structure,

and the like which the system of the Amended Invention has (hereinafter, referred to as "structure and the like").

In the description of the present application, it is described that "devices for performing RIC are known in the art" ([0040]), and, in the description of the present application and the drawings, it is not described that the "device" included in the system of the Amended Invention is a device that has a structure and the like different from those of the device of Cited Invention in order to be applied to the above-mentioned specific "subject" and "treatment"; that is, a "particularly suitable structure and the like" for the above specific "subject" and "treatment".

Then, from the descriptions in Cited Document 1 that, "Ischemic diseases are ... Ischemia and reperfusion disturbs microcirculation and leads to tissue damage and organ dysfunction. Organs such as the kidney, heart, liver, pancreas, lung, brain, and intestine are known to be damaged after ischemia and reperfusion." ([0002] of Described matter (1b)), it can be said that an examinee (subject) in Cited Invention includes "a subject that experiences ischemia/reperfusion injury" that is a subject excluded in the Amended Invention, but there is no description, in Cited Document 1, to the effect that an examinee (subject) in Cited Invention is only limited to "a subject that experiences ischemia/reperfusion injury" in question, and, therefore, it can be said that the system of Cited Invention is a system usable for a subject in the Amended Invention.

In addition, "long-term RIC" of the Amended Invention includes "at least one time of RIC treatment per day", and, in the description of the present application, it is described that "the long-term RIC refers to performing RIC regimen (the RIC regimen itself can include ischemia and reperfusion of one, two, three, four, five, or more cycles) twice or more over a period exceeding a day." ([0041]), whereas, in Cited Document 1, it is described regarding remote preconditioning of Cited Invention that "The treatment cycles of the treatment protocol may be any number of times. As described herein, a common treatment cycle may simply be repeated two, three, four or more times, until completion of the treatment protocol." (Described matter (1i)), and, therefore, there is no description to the effect that the frequency to perform the relevant remote preconditioning is limited to less than one time per day, and, further, there is no description to the effect that the number of days to perform the remote preconditioning is limited within one day that is a number of days that cannot be said to be a long-term; therefore, it can be said that the system of Cited Invention is a system usable for "long-term RIC" including "at least one time of RIC treatment per day".

Then, it cannot be said that it is obvious that the structure and the like of the system of the Amended Invention for which "subject" and "treatment" are specified as

the above-mentioned (Different Feature 1) and (Different Feature 2) are different from the structure and the like of the system of Cited Invention for which "subject" and "treatment" are not specified as the above-mentioned (Different Feature 1) and (Different Feature 2).

As above, it cannot be said that both of the above-mentioned (Different Feature 1) and (Different Feature 2) are substantive different features as a "product", which is a system, itself, because these are not matters that specify a "particularly suitable structure and the like" for the above-mentioned specific "subject" and "treatment" in the system of the Amended Invention.

Therefore, between the Amended Invention and Cited Invention, there is no substantive difference as an invention of a "product".

F As the above A to E, since there is no substantive difference as an invention of a "product" between the Amended Invention and Cited Invention, the Amended Invention is an invention described in Cited Document 1, and falls under Article 29(1)(iii) of the Patent Act; therefore, the Appellant should not be granted a patent for that independently at the time of patent application.

4 Closing Regarding the Amendment

Accordingly, the Amendment violates the provisions of Article 126(7) of the Patent Act as applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the same Act, and, therefore, it should be dismissed under the provisions of Article 53(1) of the same Act which is applied mutatis mutandis by replacing certain terms pursuant to the provisions of Article 159(1) of the same Act.

No. 3 Regarding the invention

1 The Invention

Since the amendment made on Jan. 4, 2019 has been dismissed as instructed in the above-mentioned "No. 2", the inventions according to the scope of claims of the present application are ones that are specified by the matters recited in Claims 1 to 11 of the scope of claims amended by the written amendment received on Jul. 9, 2018, and the Invention according to Claim 1 thereof (hereinafter, referred to as "the Invention") is as follows.

" [Claim 1]

A system for use in treatment of a subject having a pathological condition or being at risk of developing a pathological condition for which autophagy enhancement is effective, the system comprising

a device for performing remote ischemic conditioning (RIC), wherein

the treatment includes performing long-term RIC on the subject by the device for performing RIC, wherein

the device for performing RIC includes:

a cuff constituted so as to contract around a limb of the subject;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb; and

a controller to control the actuator in accordance with a treatment protocol, and wherein

as the subject, a subject that experiences ischemia/reperfusion injury is excluded."

2 Reasons for refusal stated in the examiner's decision

The outline of the reasons for refusal stated in the examiner's decision against the Invention are, as described in the written notice of reasons for refusal as of Dec. 25, 2017: Reason 1 that says that the Invention does not have novelty because it is an invention described in Cited Document 1 (National Publication of International Patent Application No. 2010-512176) (Article 29(1)(iii) of the Patent Act); Reason 3 that says that the detailed description of the invention of the present application is not made clear and sufficient to the extent that a person skilled in the art can carry out the Invention (Article 36(4)(i) of the Patent Act); and Reason 4 that says that the Invention is not one that is described in the detailed description of the invention of the present application (Article 36(6)(i) of the Patent Act).

3 Matters described in Cited Document 1, and Cited Invention (the invention described in Cited Document 1)

The matters described in Cited Document 1 (National Publication of International Patent Application No. 2010-512176) cited in the reasons for refusal stated in the examiner's decision are as have been described in the above-mentioned No. 2 [Reason]2(2)A.

Then, the Invention described in Cited Document 1 (hereinafter, referred to as

"Cited Invention") is as follows as has been instructed in the above-mentioned No. 2 [Reason]2(2)B.

"A system for use in treatment of an examinee comprising

a device for performing remote preconditioning, wherein

the treatment includes performing remote preconditioning on the examinee by the device, wherein

the device for performing remote preconditioning includes:

a cuff configured to contract around a limb of the examinee;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the examinee to reduce bloodstream passing through the limb; and

a controller for controlling the actuator according to a treatment protocol including a plurality of treatment cycles, wherein each of the treatment cycles includes:

cuff actuation in which the actuator causes the cuff around the limb of the examinee to contract to a pressure above a systolic pressure to occlude the blood flow of the limb;

an ischemic period in which the actuator maintains the cuff around the limb at a set value higher than the systolic pressure to occlude the blood flow of the limb and continues the maintained state for at least five seconds;

pressure releasing in which the actuator releases the cuff to allow the blood flow of the limb; and

a reperfusion period in which the cuff is held around the limb in a relaxed state to allow the blood flow of the limb, and that lasts at least one minute."

4 Comparison / Judgment between the Invention and Cited Invention

As with the above-mentioned No. 2 [Reason]2(2)C(A), "remote preconditioning" and "examinee" in Cited Invention correspond to "remote ischemic conditioning (RIC)" and "subject" in the Invention.

As with the above-mentioned No. 2 [Reason]2(2)C(B) and (C), "a cuff configured to contract around a limb of the examinee", "an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the examinee to reduce bloodstream passing through the limb", and "a controller for controlling the actuator according to a treatment protocol including a plurality of treatment cycles" of Cited Invention respectively correspond to "a cuff constituted so as to contract around a limb of the subject", "an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb",

and "a controller to control the actuator in accordance with a treatment protocol" in the Invention.

Then, the Invention and Cited Invention are identical in a point of "A system for use in treatment of a subject, the system comprising

a device for performing remote ischemic conditioning (RIC), wherein

the device for performing RIC includes:

a cuff constituted so as to contract around a limb of the subject;

an actuator coupled to the cuff for, when operating, making the cuff contract around the limb of the subject to reduce bloodstream passing through the limb; and

a controller to control the actuator in accordance with a treatment protocol.", and are different in the following points, although not quite satisfactorily.

(Different Feature 1) In the Invention, "subject" is a "subject having a pathological condition or being at risk of developing a pathological condition for which autophagy enhancement is effective", and, as the subject, "a subject that experiences ischemia/reperfusion injury is excluded" is specified, whereas, in Cited Invention, "subject" is not specified as such.

(Different Feature 2) In the Invention, it is specified that "treatment" "includes performing long-term RIC on the subject by the device for performing RIC", whereas, in Cited Invention, "treatment" is not specified as such.

The above-mentioned different features are examined.

Both of the Invention and Cited Invention are inventions of "a system for use in treatment of a subject" including "a device for performing remote ischemic conditioning (RIC)" having the above-mentioned "cuff", "actuator", and "controller".

Then, both of the matter that specifies "subject" in the Invention (the above-mentioned (Different Feature 1)) and the matter that specifies "treatment" (the above-mentioned (Different Feature 2)) are matters that specify methods for using the system of the Invention, and are not matters that specify the shape, structure, and the like of the system of the Invention (hereinafter, referred to as "structure and the like"). In the description of the present application, it is described that "devices for performing RIC are known in the art" ([0040]), and, in the description of the present application and the drawings, it is not described that the "device" included in the system of the Invention has a structure and the like different from those of the device of Cited Invention in order to be applied to the above-mentioned specific "subject" and "treatment"; that is, a "particularly suitable structure and the like" for the above specific "subject" and

"treatment".

Then, from the description in Cited Document 1 that, "Ischemic diseases are ... Ischemia and reperfusion disturbs microcirculation and leads to tissue damage and organ dysfunction. Organs such as the kidney, heart, liver, pancreas, lung, brain, and intestine are known to be damaged after ischemia and reperfusion." ([0002] of Described matter (1b)), it can be said that an examinee (subject) in Cited Invention includes "a subject that experiences ischemia/reperfusion injury" that is a subject excluded in the Invention, but since there is no description, in Cited Document 1, to the effect that an examinee (subject) in Cited Invention is only limited to "a subject that experiences ischemia/reperfusion injury" in question, it can be said that the system of Cited Invention is a system usable for a subject in the Invention.

In addition, regarding "long-term RIC" in the Invention, it is described in the description of the present application that "long-term RIC refers to performing RIC regimen (the RIC regimen itself can include ischemia and reperfusion of one, two, three, four, five, or more cycles) twice or more over a period exceeding a day." ([0041]); however, in Cited Document 1, it is described regarding remote preconditioning of Cited Invention that "The treatment cycles of the treatment protocol may be any number of times. As described herein, a common treatment cycle may simply be repeated two, three, four, or more times, until completion of the treatment protocol." (Described matter (1i)), however there is no description to the effect that the number of days to perform remote preconditioning is limited to within one day that is a number of days that cannot be said to be a long-term, and thus it can be said that the system of Cited Invention is a system usable for "long-term RIC".

Then, it cannot be said that it is obvious that the structure and the like of a system of the Invention for which "subject" and "treatment" are specified as the above-mentioned (Different Feature 1) and (Different Feature 2) are different from the structure and the like of the system of Cited Invention for which "subject" and "treatment" are not specified as the above-mentioned (Different Feature 1) and (Different Feature 2).

As above, it cannot be said that both of the above-mentioned (Different Feature 1) and (Different Feature 2) are substantive different features, because these are not matters that specify a "particularly suitable structure and the like" for the above-mentioned specific "subject" and "treatment" in the system of the Invention.

Therefore, between the Invention and Cited Invention, there is no substantive difference as an invention of a "product".

5 As the above 1 to 4, because there is no substantive difference as an invention of a "product" between the Invention and Cited Invention, The Invention is an invention described in Cited Document 1, falls under Article 29(1)(iii) of the Patent Act, and the Appellant should not be granted a patent for that.

No. 4 Appellant's allegation

The Appellant alleges as follows in "(Reason that the Invention has novelty)" of "Statement of the request 3. Reason that the Invention should be patented" of the written request for appeal amended by the written amendment (form) received on Jan. 30, 2019.

"In other words, the Invention has been made focusing on new use of a system to perform RIC. Therefore, we consider that judgment on novelty and inventive step of the Invention should be performed as a 'use invention'; that is, 'an invention based on (i) discovery of unknown attribute of some product, and (ii) finding out that the product is better suited for use in a new use by this attribute', based on its use. Note that, it is described, in Examination Guidelines for Patent and Utility Model, Part III, Chapter 2, Section 4 'Handling of claims and the like having particular expression', '(2) Machine, instrument, article, apparatus etc.', that 'Usually, a way of thinking of the use invention of 3.1.2 is never applied. This is because, usually, a product and its use are integral.' However, in the case of the Invention, taking into consideration that the Invention is associated with medical care, we consider that it should not be recognized in a way that 'a product and its use are integral' in a uniform manner. The reason of this is that, if it is an invention that is not related to medical care, it is possible for an inventor who has found a new use of an apparatus to select acquisition of the right of the relevant invention also as an invention of a 'method', however, in the Invention, when it is filed as an invention of a 'method', it is judged as 'an invention of a method of performing surgery, therapy or diagnosis of humans', and thus it becomes difficult to acquire the right. In the above-mentioned examination guideline, as described as 'usually', it is not required to recognize the matter that 'a product and its use are integral' in a uniform manner in all inventions. In the Invention, the use of 'a system that includes a cuff, actuator, and controller, and performs remote ischemic conditioning' is obviously different from the use of Cited Document 1. In the Invention, in view of the distinctive feature of the Invention, we consider that, by a way of thinking similar to that of pharmaceutical compositions, for example, 'use invention' of a system should be admitted."

Therefore, the above-mentioned allegation is discussed below.

As instructed in the above-mentioned "No. 2, [Reason]3(3)E] and "No. 3, 4", although there is no substantive difference between the Amended Invention (or the Invention) and Cited Invention as an invention of a "product", just in case, whether or not there is room for understanding the Amended Invention (or the Invention) being a use invention will be discussed below.

A use invention means an invention based on (i) discovery of unknown attribute of some product, and (ii) finding out that the product is better suited for use in a new use by this attribute (refer to Examination Guidelines for Patent and Utility Model, Part III, Chapter 2, Section 4 "Handling of claims and the like having particular expression", "3.1.2 Way of thinking when an invention of a product to which use limitation is given should be construed as a use invention").

In the above-mentioned Appellant's allegation, the specific content of a "unknown attribute" which the system of the Amended Invention (or the Invention) has is not indicated; however even if, from the description of "performing long-term RIC every day on the subject by the device for performing RIC" in the Amended Invention, the system of the Amended Invention has an attribute as "performing long-term RIC on a subject", the system of Cited Invention is a system usable for "long-term RIC" including "at least one time of RIC treatment per day" as instructed in the above-mentioned "No. 2 [Reason] 3(3)E], and, therefore, the above-mentioned attribute of "performing long-term RIC on a subject" is nothing but a known attribute described in Cited Document 1 and thus it cannot be said that it is an "unknown attribute".

Then, the matter as "for use in treatment of a subject having a pathological condition for which autophagy enhancement is effective" in the Amended Invention is nothing but a one that describes the purpose of performing the long-term RIC every day by the system of the Amended Invention, and thus the relevant matter is not one that specifies a "unknown attribute" which the system of the Amended Invention has.

Furthermore, the matter that "execution of the long-term RIC provides enhancement of an autophagy level in the subject" in the Amended Invention is nothing but a matter indicating a phenomenon of enhancement of an autophagy level caused as a result of carrying out long-term RIC on a subject in the relevant "subject"; that is, "various kinds of animals including a human" (refer to [0032] of the description of the present application), and is not one that indicates a phenomenon formed in the system itself of the Amended Invention; therefore, the relevant matter is not a matter that specifies an "unknown attribute" which the system of the Amended Invention has.

In this way, it cannot be said that the system of the Amended Invention is a

system having an "unknown attribute", and, by the similar reason, it cannot be said that the system of the Invention is one having an "unknown attribute", and thus there is no room for understanding as both of the Amended Invention and the Invention are use inventions.

Therefore, the above-mentioned Appellant's allegation cannot be acknowledged.

No. 5 Closing

As above, since the invention according to Claim 1 of the present application falls under Article 29(1)(iii) of the Patent Act, and the Appellant should not be granted a patent for that, the present application should be rejected without examining the inventions according to the other claims.

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

June 18, 2020

Chief administrative judge: INOUE, Noriyuki
Administrative judge: MAEDA, Kayoko
Administrative judge: FUCHINO, Ruka