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Datasheet for the decision of 2 March 2026

Case Number: T 0268/24 - 3.5.06

Application Number: 16737933.8

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Language of the proceedings: EN

Title of invention:

DEVICES FOR ESTIMATING REGIONAL METABOLIC RATE OF ORGANS BASED ON HEAT GENERATION AND FOR ESTIMATING REGIONAL BLOOD FLOW(S) FOR THE VOLUME(S) OF TISSUE PERFUSED

Applicant:

Hybernia Medical LLC

Headword:

Brain perfusion/HYBERNIA

Relevant legal provisions:

EPC Art. 54, 56, 123(2), 84
RPBA 2020 Art. 12(6)

Keyword:

Amendments - added subject-matter (yes)
Novelty - (yes)
Inventive step - (no)
Claims - clarity (no)
Late-filed request - should have been submitted in first-instance proceedings (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0268/24 - 3.5.06

D E C I S I O N
of Technical Board of Appeal 3.5.06
of 2 March 2026

Appellant: (Applicant)	Hybernia Medical LLC 659 Ely Avenue Pelham, NY 10803 (US)
Representative:	Wynne-Jones IP Limited Office 16A The Maltings East Tyndall Street Cardiff, CF24 5EZ (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 October 2023 refusing European patent application No. 16737933.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Müller
Members:	G. Zucka
	A. Jimenez

Summary of Facts and Submissions

I. The appeal is against the decision by the examining division, dispatched with reasons on 6 October 2023, to refuse European patent application 16737933.8, on the basis that the application did not satisfy the requirements of Articles 123(2) and 54 EPC. The present decision refers to the following document cited during the first instance proceedings:

D1: US 2013/331916 A1.

II. A notice of appeal was received on 6 December 2023, the appeal fee being paid on the same day. A statement of grounds of appeal was received on 6 February 2024.

III. The appellant requested that the decision of the examining division to refuse the application be set aside and a patent be granted on the basis of the claims of the main request underlying the decision under appeal or of one of two auxiliary requests, all (re-)filed with the statement of grounds of appeal.

IV. The further text on file is:

description pages
1 to 24 as published;

drawing sheets
1 to 20 as published.

V. The board issued a summons to oral proceedings. In the attached communication under Article 15(1) RPBA, the

board set out its preliminary opinion, according to which the appealed decision should be upheld.

VI. The appellant did not respond to the board's preliminary opinion in substance but, in a letter received on 25 February 2026, informed the board that it would not be present at the oral proceedings. The board subsequently cancelled those proceedings.

VII. Claim 1 of the main request reads as follows:

"A system comprising:

a controller (22);

an insertion device (2) comprising at least one temperatures sensor thereon, the insertion device (2) functionally coupled to the controller (22) to provide a plurality of temperature measurement of a subject’s brain to the controller (22);

a pump (24) functionally coupled to the controller (22) for the controller to vary an infusate flow rate to induce temperature changes in at least a portion of the subject’s brain,

characterized in that the infusate flow rate is varied according to sequence and timing instructions to induce temperature changes in at least the portion of the subject’s brain in accordance with at least one of a wash-in and a wash-out cycle, in which the controller (22) varies the pump (24) to induce temperature changes of at least a portion of the subject’s brain in a sequence that comprises lowering the temperature of the brain by at least one step in temperature to an equilibrium temperature, maintaining the equilibrium temperature for a given time, and raising the temperature of the brain to a temperature above the equilibrium temperature;

a memory device functionally coupled to the controller (22), the controller operable to store the plurality of measurements of the temperature of the subject’s brain to the controller taken throughout the at least one of the wash-in and wash-out perfusion induced temperature changes in at least a portion of the subject’s brain, and further operable to estimate values for at least one hemodynamic characteristic of at least a portion of the subject’s brain based on the plurality of temperature measurements obtained during the perfusion induced temperature changes and time as a variable."

VIII. The wording of the other claims of the main and the auxiliary requests is not relevant for the present decision.

Reasons for the Decision

1. *The application*

1.1 The application relates to the estimation of regional metabolic rate and blood flows of a subject's organ (more specifically the brain) during endovascular interventions (description par. [0001]).

1.2 The application allegedly aims to solve several issues associated with the current diagnostic paradigm in acute ischaemic stroke (par. [0006]):
- Imaging systems only provide a "snapshot" of an organ's metabolic rate at a given time. This provides an incomplete "snapshot" of the processes involved in ischaemic tissue damage.

- Repetitive brain imaging or monitoring during reperfusion therapy is not practical or economical.
- In patients selected for endovascular recanalisation therapy (ERT), further assessments of organ physiology and ischaemic damage cannot be performed during the entire intervention (presumably because this would significantly interrupt or delay the therapy).

It is, however, not clear from the description which problem is solved by the features of claim 1.

1.3 According to the applicant's letter received on 11 September 2019 (second page, first paragraph) during the examination proceedings, the cooling and heating sequence used in the application (viz. cooling - equilibrium - raising the temperature; *ibid.*, first page, fourth paragraph) is said to avoid damaging the organ and to improve drug effectiveness while minimising toxicity.

Such sequence would correspond to the features in the penultimate paragraph of claim 1. The board understands that, in a medical context, "wash-in" refers to the initial increase of a substance (here: the infusate) in a specific tissue (here: the brain), while "wash-out" refers to the subsequent decrease of that substance as it clears.

1.4 The last paragraph of the claim contains additional features comprising an estimation of values of a haemodynamic characteristic. Neither the description nor the appellant explain how these features contribute to the solution of the indicated problem or of another problem altogether. The board assumes that said value could for instance be the haematocrit, and that the estimation of the haematocrit could be used in a

feedback loop, where the temperature of the infusate would, when necessary, be increased to keep the haematocrit above a certain minimum (cf. D1, par. [0148]).

2. *Main request - clarity; Article 84 EPC*

2.1 In claim 1 of the main request, it is not clear whether the expression "at least a portion of the subject's brain" in the phrase "to induce temperature changes of a least a portion of the subject's brain in a sequence..." refers to the same portion as mentioned before in the claim.

The same is true for the same expression in the last paragraph of the claim.

2.2 It is not clear whether the expression "and time as a variable" in the phrase "estimate values for at least one hemodynamic characteristic of at least a portion of the subject’s brain based on the plurality of temperature measurements obtained during the perfusion induced temperature changes and time as a variable" refers to discrete time points of individual measurements or to e.g. the duration of specific phases (e.g. wash-in, equilibrium, wash-out cycles).

If a reference to discrete time points of individual measurements is intended, it is not clear in which sense the expression limits the estimation of the haemodynamic characteristics, given that the temperature measurements will inherently in any case take place at certain times.

2.3 For the above reasons, the main request does not satisfy the requirements of Article 84 EPC.

3. *Added subject-matter; Article 123(2) EPC*

3.1 According to the appealed decision (Reasons 1), there is no clear and unambiguous basis for the amendment "[...] and time as a variable" in the original application documents.

3.2 According to the appellant (statement of grounds of appeal, points 2.2 and 2.3) the original description paragraph [0043] refers to "operating parameters", i.e variables, which may include "time".

3.3 The board concedes that said paragraph as well as par. [0074] which is also cited by the appellant disclose "time" as a variable at least in some sense.

However, neither cited paragraph nor any other paragraph provides a basis for "time as a variable" to be used for the estimation of haemodynamic characteristics, as required by the claim.

3.4 The board, therefore, holds that claim 1 does not satisfy the requirements of Article 123(2) EPC.

4. *Novelty; Article 54 EPC*

4.1 Document D1 discloses a system comprising a controller (Figure 2: 22) and an insertion device (2) comprising at least one temperatures sensor (10a-10d) thereon, the insertion device (2) functionally coupled to the controller (22) to provide a plurality of temperature measurements of a subject’s brain (par. [0002]) to the controller (22); see par. [0126].

4.2 The system comprises a pump (24) functionally coupled to the controller (22) for the controller to vary an

infusate flow rate to induce temperature changes in at least a portion of the subject's brain; see par. [0124].

4.3 It can be said that the infusate flow rate is varied to induce temperature changes in at least the portion of the subject's brain, wherein the controller (22) varies the pump (24) to induce temperature changes of at least a portion of the subject's brain in a sequence that comprises lowering the temperature of the brain by at least one step in temperature to an equilibrium temperature (par. [0164]: "target temperature"), maintaining the equilibrium temperature for a given time, and raising the temperature of the brain to a temperature above the equilibrium temperature (i.e. when infusion is stopped; see par. [0164], last sentence).

It can also be said that this constitutes a "wash-in" and a "wash-out" cycle. It can further be said that this constitutes a sequence of events, and that these events will occur at certain moments according to a manual or an automatic decision, i.e. "sequence and timing instructions" are provided in the system of D1.

4.4 According to the appealed decision (Reasons 2.1, last paragraph), it follows from par. [0171] in D1 that some kind of temporary storing is implicit when calculating the haemodynamic parameter.

Presumably, this statement refers to a storing of the values T_1, T_2 and T_4 in the equation $X = IR*(T_1-T_2)/(T_4-T_1)$, which is used to calculate the dilution factor and the haematocrit.

However, there is firstly no indication that the values T_1, T_2 and T_4 correspond to a plurality of measurements of the temperature of the subject's brain. It would rather seem, as is visible in e.g. figure 2 and described in the description of D1, that the values T_1 to T_4 are the temperatures of the infusate measured at different locations by the sensors 10a to 10d.

Secondly, the calculation of $(T_1-T_2)/(T_4-T_1)$ does not necessarily require storing the values T_1, T_2 and T_4. Those three values (transmitted by sensors 10a, 10b and 10d) could, in principle, be fed as input to a dedicated circuit performing the calculation. No storage of T_1, T_2 and T_4 would have to be involved in such a system.

D1, therefore, does not disclose or imply a memory device functionally coupled to the controller, the controller operable to store the plurality of measurements of the temperature of the subject's brain to the controller taken throughout the at least one of the wash-in and wash-out perfusion induced temperature changes in at least a portion of the subject's brain.

4.5 Further, given that T_1, T_2 and T_4 in D1 do not correspond to measurements of the temperature of the subject's brain, it cannot be said that par. [0171] discloses that the controller is operable to estimate values for a haemodynamic characteristic based on a plurality of temperature measurements of the subject's brain, as required by claim 1.

4.6 The board consequently holds that the subject-matter of claim 1 of the main request is novel (Article 54 EPC).

5. *Inventive step; Article 56 EPC*

5.1 According to the applicant's letter received on 11 September 2019 during the examination proceedings (second page, first paragraph), the cooling and heating sequence used in the application (viz. cooling - equilibrium - raising the temperature; *ibid.*, first page, fourth paragraph) is said to avoid damaging the organ and to improve drug effectiveness while minimising toxicity.

Such a cooling and heating sequence is, however, also used in the system of D1 (see 4.3 above).

5.2 One may, furthermore, reasonably assume that the skilled person will want to estimate haemodynamic characteristics of a subject's brain and will to this end use temperature measurements of the subject's brain acquired during the wash-in, equilibrium, wash-out cycles disclosed in D1, i.e. measurements at different moments ("time as a variable") which need to be stored at least temporarily in a memory device coupled to the controller in order for the controller to estimate said haemodynamic characteristics.

5.3 The skilled person will thus arrive at the subject-matter of claim 1 without the need for an inventive step. The board, therefore, holds that the subject-matter of claim 1 of the main request is not inventive (Article 56 EPC).

6. *Admittance of the auxiliary requests*

6.1 The board understands from the statement of grounds of appeal (points 4.1, 4.2, 6.1 and 6.2, the latter two incorrectly also numbered "4.1" and "4.2") that the

appellant filed the claims of auxiliary request 1 (labelled "first main request") and auxiliary request 2 (labelled "second auxiliary request") in response to point 1 in the reasons for the appealed decision, according to which claim 1 of then the sole request contained added subject-matter (Article 123(2) EPC).

6.2 The board notes that said reasoning in the appealed decision is identical to the reasoning given under point 3 of the annex to the summons for oral proceedings before the examining division dated 15 March 2023.

This means that the applicant already could and should have filed one or more auxiliary requests dealing with this objection during the examination proceedings, viz. in response to the summons or exceptionally at the oral proceedings.

6.3 The appellant has further not argued that the circumstances of the appeal case would justify the admittance of the auxiliary requests. The board from its side cannot see such arguments.

6.4 The board additionally notes that the expression "and the timing thereof" has the same meaning as "and time as a variable" and that the amendments which were introduced *prima facie* do not overcome the objection for added subject-matter from the examining division.

The amendments, which only addressed the objection for added subject-matter, *prima facie* also do not overcome the above objections under Articles 84 and 56 EPC.

6.5 The board, therefore, does not admit auxiliary requests 1 and 2 into the appeal proceedings (Article 12(6) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Stridde M. Müller

Decision electronically authenticated