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Datasheet for the decision of 26 January 2011

| Case Number: | T 1222/07 - 3.2.02 | | | |
|------------------------------|--------------------|--|--|--|
| Application Number: | 01930574.7 | | | |
| Publication Number: | 1276521 | | | |
| IPC: | A61M 1/36 | | | |
| Language of the proceedings: | EN | | | |

Title of invention:

Low extracorporeal volume treatment system

Applicant: THERAKOS, INC.

INERAROS, IN

Opponent:

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Headword:

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Relevant legal provisions: EPC Art. 123(2), 84, 111

Relevant legal provisions (EPC 1973):

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Keyword:
"Extension of subject-matter (no)"
"Clarity (yes)"
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Decisions cited:

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Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 1222/07 - 3.2.02

DECISION of the Technical Board of Appeal 3.2.02 of 26 January 2011

| Appellant: | THERAKOS, INC. 437 Creamery Way Exton, PA 19341 (US) | |
|------------------------|--|--|
| Representative: | Mercer, Christopher Paul Carpmaels & Ransford One Southampton Row London WC1B 5HA (GB) | |
| Decision under appeal: | Decision of the Examining Division of the European Patent Office posted 1 March 2007 refusing European patent application No. 01930574.7 pursuant to Article 97(2) EPC. | |

Composition of the Board:

| Chairman: | М. | Noël | | |
|-----------|----|------------|----|-------|
| Members: | P. | L. | P. | Weber |
| | Α. | Pignatelli | | |

Summary of Facts and Submissions

- I. The appeal is directed against the decision of the Examining Division posted on 1 March 2007 to refuse European patent application No. 01930574.7
- II. Notice of appeal was filed on 4 May 2007 and the appeal fee paid on the same day.

The statement setting out the grounds of appeal was filed on 11 July 2007.

III. The appellant requests that the decision be set aside and that a patent be granted on the basis of the set of claims 1 to 19 according to the main request or according to the auxiliary request, both filed with the statement setting out the grounds of appeal.

> Oral proceedings are requested in case the Board feels minded not to maintain the patent on the basis of the claims in the main request.

As specified by the appellant in a phone conversation held on 24 January 2011, oral proceedings are however not requested in case the Board intends to send the case back to the department of the first instance for further prosecution.

IV. According to the impugned decision the application was refused because none of the three requests on file at that date (main request, first auxiliary request, second auxiliary request) satisfied the formal requirements of Articles 84 and/or 123(2) EPC. Claim 1 according to the refused second auxiliary request reads as follows:

"1. A system for regulating a photopheresis treatment process for reducing the net fluid volume deficiency in a patient, comprising:

a centrifuge (160) containing a centrifuge bowl (161) that separates the buffy coat from the other components of blood (110);

means for transferring buffy coat from the centrifuge bowl (161) to a buffy coat chamber (180);

a storage chamber (170) for storing red blood cells and plasma separated in the centrifuge(160);

a load cell (175) associated with the storage chamber (170) for measuring the weight of the storage chamber (170) and thereby determining the net fluid volume change in said patient (175);

means for adjusting said net fluid volume deficiency of said patient so that the minimum net fluid volume deficiency is obtained (175/185/186/190/200/205/210/220); and

means for maintaining said minimum net fluid volume deficiency in said patient (175/185/186/190/200/205/210/220)."

(a) Concerning the refused second auxiliary request the following can be read in the decision:

"Claim 1 second auxiliary request is refused for two infringements of Article 123(2) EPC. Claim 1 first line "A system for REGULATING a photophoresis treatment process ... " Neither the system in figure 1 nor any other system originally suggested REGULATES photophoresis, this system is merely for regulating fluid deficiency. On the contrary photophoresis takes place LATER and at a different place than the system in fig 1 see page 5 line 6: "... where it AWAITS photophoresis treatment" page 8 line 10 "... where it AWAITS treatment". The second infringement of Article 123(2) EPC is in claim 1 fifth line: "means for transferring buffy coat from the centrifuge ... to chamber 180". This means may well be a pump or some cassette but originally merely transfer via line 121 fig 1 or manual transfer was suggested see page 5 line 6: "from centrifuge bowl 161 ... in fluid communication with line 121", page 8 line 9 "centrifuge bowl 161 ... components are manually removed"."

(b) Concerning the main request as refused the following can be read in the decision in relation to the "adjusting means" feature:

"Claim 1 - main request was also considered to lack clarity, Article 84 EPC, because the above "means for adjusting" is defined solely by the desired result without indicating any concrete constructional features." V. In its statement of the grounds of appeal the appellant explains that the main request filed therewith is based on the refused second auxiliary request, the features considered to infringe Article 123(2) EPC having been removed.

> The appellant further mentions the basis in the application as filed for the remaining features of claim 1 and explains that the wording of the "means for adjusting feature" was set back to the wording of the feature in originally filed claim 28, so that the clarity objection made by the Examining Division was no longer applicable.

VI. Claim 1 according to the main request in the appeal proceedings reads as follows (references of the features added by the Board):

"a) A system for reducing the net fluid volume deficiency in a patient during a photophoresis treatment process, comprising:

b) a centrifuge (160) containing a centrifuge bowl (161) that separates the buffy coat from other components of blood (110);

c) a storage chamber (170) for storing red blood cells and plasma separated in the centrifuge (160);

d) a load cell (175) associated with the storage chamber (170) for measuring the weight of the storage chamber (170) and thereby determining the net fluid volume deficiency in said patient (175); e) means for adjusting said net fluid volume deficiency of said patient so that the minimum net fluid volume deficiency is obtained (175/185/186/190/200/205/210/220); and

f) means for maintaining said minimum net fluid volume deficiency in said patient (175/185/186/190/200/205/210/220)."

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Article 123(2) EPC.
- 2.1 In the present case the only objection raised by the Examining Division against claim 1 according to the second auxiliary request in the examining procedure was that the claim infringed Article 123(2) EPC because two of its features were not disclosed in the originally filed application documents.

The remaining features were not objected to.

2.2 Claim 1 according to main request as filed in the appeal proceedings corresponds to claim 1 according to the second auxiliary request as refused but without the features the first instance department considered to infringe Article 123(2) EPC. Hence, the objection of the Examining Division does not apply any longer to present claim 1.

2.3 Originally filed claim 28 reads as follows:

"A system for regulating a medical treatment process for reducing the net fluid volume deficiency in a patient, comprising: means for determining the net fluid volume change in said patient; means for adjusting said net fluid volume deficiency of said patient so that the minimum net fluid volume deficiency is obtained; and means for maintaining said minimum net fluid volume deficiency in said patient."

Starting from originally filed claim 28, the features of claim 1 according to the main request are disclosed in the originally filed application documents in the following manner:

i) Feature a) no longer mentions that the system is for regulating a medical treatment process. Instead it is now mentioned that the reduction of the net fluid volume deficiency takes place during a photophoresis treatment process.

That the system is for use during a photophoresis process is already mentioned in the introductory part of the description when the prior art is described, see page 1, line 13 and line 16, and also further in the description page 5, lines 5 to 7, where it is made clear that the buffy coat is stored in chamber 180, where it awaits photophoresis treatment. Hence, it is disclosed in the originally filed application documents that the system for reducing the net fluid volume deficiency in a patient is for use during a photophoresis treatment process.

ii) The means for determining the net fluid volume change in said patient is no longer mentioned in such general terms, but is defined more precisely, namely by defining in feature d) that the load cell is used for determining the net fluid volume deficiency.

This feature is disclosed for instance in originally filed claim 29, or in the originally filed description on page 2, lines 27, 28; page 5, lines 20 to 25; page 7, lines 18 to 20, or page 8, lines 12, 13.

iii) Features b), according to which the system includes a centrifuge containing a centrifuge bowl that separates the buffy coat from other components of blood, is disclosed for instance in the figures, on page 4, lines 28, 29, or page 5 lines 1 to 3.

iv) Feature c), according to which the system includes a storage chamber for storing red blood cells and plasma separated in the centrifuge, is disclosed for instance on page 5, lines 15 to 17.

v) Features e) and f) are identical to the corresponding ones in originally filed claim 28.

2.4 Claims 2 to 19 of the main request respectively correspond to originally filed claims 30 to 52, the order of the claims having been changed slightly, and present claims 5,6,7,8 having a double dependency corresponding respectively to originally filed claims 32/37, 33/38, 34/39, 35/40.

- 2.5 The set of claims according to the main request thus fulfils the requirements of Article 123(2) EPC.
- 3. Article 84 EPC
- 3.1 In its decision to refuse the application the Examining Division considered that the general definition of the adjusting means given in claim 1 of the main request and in claim 1 of the first auxiliary request infringed Article 84 EPC as the wording of that feature corresponded to a definition by a result to be achieved without indication of concrete constructional features.

It is not clear to the Board whether when taking its decision the Examining Division maintained this objection against claim 1 of the second auxiliary request, since the Examining Division did not mention this lack of clarity objection under point III of the decision dealing with the second auxiliary request, and since the wording of the objected feature was slightly different.

However, for the sake of completeness and to avoid possible unnecessary back and forth of the case between the first and second instances, the Board will take position on clarity as allowed by the EPC under Article 111 EPC.

3.2 As a general preliminary remark, the Board would like to point out that almost any definition of a feature by its function (functional definition) amounts to a definition by the result to be achieved, since such a functional definition of a feature defines the function

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the feature has to fulfil and not the specific means needed to fulfil the function. Such functional definitions are widely used and accepted for the definition of features in claims as long as the person skilled in the art knows, without exceeding his normal skills and knowledge, what he has to do in order to obtain said result (see case law 6th edition 2010 II.B.1.2.2). This means that the simple fact of defining a feature by the result which is intended to be achieved with it, cannot, per se, be a reason of infringement of Article 84 EPC.

It seems that, provided there is sufficient support for it in the description and unless the result which is mentioned is not clear as such, such a definition by the result to be achieved or by the function to be fulfilled, indicating what the feature should be there for, allows for a fair protection for the applicant or inventor having described specific embodiments of its invention.

While it is accepted that in some instances such definitions might lead to a problem with Article 83 EPC, as the definition might be too broad or the result or function technically difficult to be carried out, such definitions cannot, per se, systematically be considered to be problematic under Article 84 EPC.

3.3 In the present case the feature at issue reads:

"means for adjusting said net fluid volume deficiency of said patient so that the minimum net fluid volume deficiency is obtained".

The Board cannot see any clarity problems with this feature whatsoever.

It means that some means must be provided which allow the net fluid volume deficiency to be adjusted to a minimum for the patient.

In the context of the claimed invention, it is in particular clear from the description, see page 2, line 29 to page 3 line 2 and page 3, lines 11 to 14, respectively, that:

"Adjusting the net fluid volume deficiency to obtain a minimal net fluid volume deficiency may involve increasing or decreasing the amount of biological fluid returned to a patient through use of a valving means and/or a pumping means to adjust the flow of a biological fluid. Maintaining the net fluid volume deficiency may also involve using one or more of the following: a load cell, pumping means, and valving means. Maintaining a minimal net fluid volume deficiency may also involve monitoring the net fluid volume deficiency."

and that:

" Alternatively, the system for determining, adjusting, and maintaining the minimal net fluid volume deficiency may be a controller that communicates with the load cell, valving means, and pumping means. This controller may be a computer that controls the load cell, valving means, and pumping means."

The skilled reader can therefore have no doubt as to what is meant by the adjusting means. The requirements of Article 84 are therefore met. 4. The decision under appeal was only based on noncompliance with Articles 123(2) EPC and 84 EPC, which objections are now removed. Since the Board does not consider it appropriate to investigate the case further on substantive issues not yet examined by the Examining Division, the case is remitted to the department of the first instance for further prosecution pursuant to Article 111 EPC.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside
- 2. The case is remitted to the department of the first instance for further prosecution on the basis of claims 1 to 19 of the main request filed on 11 July 2007.

The Registrar:

The Chairman:

D. Sauter

M. Noël