Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 28 November 2023

Case Number: T 1080/20 - 3.2.02

Application Number: 12850737.3

Publication Number: 2701765

IPC: A61B5/145, A61M1/16, A61B5/026, A61B5/053, A61M1/36

Language of the proceedings: EN

Title of invention:
FLUID VOLUME MONITORING FOR PATIENTS WITH RENAL DISEASE

Patent Proprietor:
Medtronic, Inc.

Opponent:
Fresenius Medical Care AG & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 69, 111(1), 123(3)
RPBA 2020 Art. 11, 12(4)

Keyword:
Amendments - broadening of claim (no)
Oral proceedings - before board of appeal - request for oral proceedings
Remittal to the department of first instance - (yes)

Decisions cited:
G 0002/88

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1080/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 28 November 2023

Appellant: (Patent Proprietor)	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 (US)
Representative:	Maschio, Antonio Maschio & Soames IP Limited 30 Carlton Crescent Southampton SO15 2EW (GB)
Respondent: (Opponent)	Fresenius Medical Care AG & Co. KGaA Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Bobbert & Partner Patentanwälte PartmbB Postfach 1252 85422 Erding (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 February 2020 revoking European patent No. 2701765 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	N. Obrovski

Summary of Facts and Submissions

I. The appeal is directed against the decision of the Opposition Division revoking European patent No. 2701765 because the subject-matter of claim 1 extended beyond the content of the application as filed.

II. Oral proceedings before the Board took place on 28 November 2023. At the end of the oral proceedings the requests were as follows:

The appellant (proprietor) requested that the decision under appeal be set aside and that the case be remitted to the Opposition Division for discussion of the substantive objections on the basis of the main request or the first auxiliary request, which were filed with the statement of grounds of appeal and labelled as "First Auxiliary Request" and "Second Auxiliary Request", respectively.

The respondent (opponent) requested that the appeal be dismissed. In the event that the decision under appeal were to be set aside, it requested remittal to the Opposition Division for discussion of the substantive objections.

III. Claims 1 and 2 of the main request (labelled "First Auxiliary Request") read as follows:

1. "A system comprising:

a blood fluid removal device (100) comprising

(i) an inlet (110) for receiving blood from a patient,

(ii) a first outlet (180) for returning blood to the patient,

(iii) a medium (130) for removing fluid and contaminants from the blood in a blood compartment of the patient, the medium being positioned between the inlet and the first outlet, wherein removal of fluid from the blood causes a flow of fluid from a tissue compartment of the patient to the blood compartment of the patient;

(iv) a fluid rate removal controller (120); and (v) a second outlet for flow of the removed fluid and contaminants; a first sensor (200) at a first location for monitoring tissue fluid in the tissue compartment of the patient for an indicator of tissue fluid volume; a second sensor (210) at a second, different location for monitoring blood fluid in the blood compartment of the patient for an indicator of blood fluid volume;

control electronics (150) in operable communication with the sensor for monitoring an indicator of tissue fluid volume, the sensor for monitoring an indicator of blood fluid volume; and the fluid rate removal controller;

and a computer readable medium comprising instructions that cause the control electronics to (i) calculate a ratio of the indicator of tissue fluid volume to the indicator of blood fluid volume based on data obtained from the first and second sensors, respectively; (ii) determine whether the calculated ratio is outside of a predetermined range; and (iii) alter the rate of fluid removal if the ratio is determined to be outside of the predetermined range."

2. "A system comprising:

a blood fluid removal device (100) comprising

(i) an inlet (110) for receiving blood from a patient,

(ii) a first outlet (180) for returning blood to the patient,

(iii) a medium (130) for removing fluid and contaminants from the blood in a blood compartment of the patient, the medium being positioned between the inlet and the first outlet, wherein removal of fluid from the blood causes a flow of fluid from a tissue compartment of the patient to the blood compartment of the patient;

(iv) a fluid rate removal controller (120); and (v) a second outlet for flow of the removed fluid and contaminants; a first sensor (200) at a first location for monitoring tissue fluid in the tissue compartment of the patient for an indicator of tissue fluid volume; a second sensor (210) at a second, different location for monitoring blood fluid in the blood compartment of the patient for an indicator of blood fluid volume;

control electronics (150) in operable communication with the sensor for monitoring an indicator of tissue fluid volume, the sensor for monitoring an indicator of blood fluid volume; and the fluid rate removal controller;

and a computer readable medium comprising instructions that cause the control electronics to (i) calculate a value indicative of tissue fluid volume based on data

obtained from the first sensor; (ii) calculate a value indicative of blood fluid volume based on data obtained from the second sensor; (iii) determine whether a ratio of the value indicative of tissue fluid volume to the value indicative of blood fluid volume is outside of a predetermined range; and (iv) alter the rate of fluid removal if the ratio is determined to be outside of the predetermined range.

IV. The appellant's arguments relevant to the present decision can be summarised as follows:

Main request - admittance

The main request should be admitted into the appeal proceedings. The appealed decision had been taken by the Opposition Division without issuing a preliminary opinion or holding oral proceedings. The main request had been filed at the outset of the appeal proceedings together with the statement of grounds of appeal. Claim 1 of the main request combined claims 1 and 2 as granted and claim 2 combined claims 1 and 3 as granted.

Main request - Article 123(3) EPC

Claim 1 as granted encompassed both determining the ratio of the indicator of tissue fluid volume to the indicator of blood fluid volume (as defined in dependent claim 2 as granted and in the embodiment of Figure 12) and determining the ratio of the value indicative of tissue fluid volume to the value indicative of blood fluid volume (as defined in dependent claim 3 as granted and in the embodiment of Figure 13). This derived not only from the claim dependency but also from the specification (e.g. paragraphs [0053], [0054] and [0059]), which made it

clear that determining the ratio of tissue fluid volume and blood fluid volume encompassed both of these alternatives.

Claim 1 of the main request was restricted to one of the options encompassed by claim 1 as granted and thus did not extend the protection conferred by claim 1 as granted.

V. The respondent's arguments relevant to the present decision can be summarised as follows:

Main request - admittance

The appeal served to review the decision of the Opposition Division. The Opposition Division had had no chance to decide on the main request, which should have been filed earlier. The main request represented a fresh case and was not *prima facie* allowable because it infringed Article 123(3) EPC.

Main request - Article 123(3) EPC

Claim 1 as granted comprised the determination of a ratio of fluid tissue volume and blood fluid volume, i.e. of two volumes measured e.g. in ml. It was clear from the specification that this was different from the determination of a ratio of indicators of those volumes, obtained for example from monitoring impedance or haematocrit levels. The specification even indicated that the two ratios might give different results. Moreover, claim 1 as granted could not be construed based on claims 2 or 3.

Claim 1 of the main request did not require the ratio to be calculated for the volumes themselves but only

for indicators of those volumes, thus resulting in an extended scope of protection. Similar reasoning applied to claim 2 of the main request. Hence the main request infringed Article 123(3) EPC.

Appellant's request for oral proceedings

The appellant's request for oral proceedings (in the appeal proceedings) was filed only after the statement of grounds of appeal had been filed. It should have been submitted already, within the meaning of Article 12(6) RPBA 2020, in the proceedings leading to the decision under appeal. The request should thus not be admitted.

Reasons for the Decision

1. Appellant's request for oral proceedings

1.1 The respondent argued that the appellant's request for oral proceedings (in the appeal proceedings) should have been submitted already, within the meaning of Article 12(6) RPBA 2020, in the proceedings leading to the decision under appeal. This argument is flawed.

1.2 A party's request for oral proceedings in the appeal proceedings is different from that party's request for oral proceedings in the proceedings before the department of first instance. If a party, as in the present case, chooses not to avail itself of its right to oral proceedings before the department of first instance, it has to bear the consequences of that choice in that it must accept that that department may decide on the basis of that party's written submissions only. This, however, does not mean that such a party is

then also barred from requesting oral proceedings in any ensuing appeal proceedings.

1.3 Hence oral proceedings were held in line with the appellant's request.

2. The patent

2.1 Errors in fluid removal during fluid removal sessions such as haemodialysis or haemofiltration may result from inaccurate determination of the patient's dry weight (i.e. the weight that the person would have if their kidneys were functioning properly) and may lead to severe risks for the patient.

2.2 The patent deals with monitoring fluid volume in blood and tissue compartments of patients during fluid removal sessions, and controlling the rate at which fluid is removed from blood based on the monitored fluid volumes. By maintaining a proper fluid balance between blood and tissue compartments, patient safety is enhanced and the efficiency of blood cleaning is increased.

3. Main request - admittance

3.1 The respondent requested that the main request not be admitted into the appeal proceedings. This request was not made in the reply to the statement of grounds of appeal but for the first time by a letter dated 29 June 2022, i.e. more than two years after the main request had been filed. The respondent argued that the main request should have been filed during the first-instance opposition proceedings, that it represented a fresh case and that it was not *prima facie* allowable because it infringed Article 123(3) EPC.

3.2 The main request was filed together with the statement of grounds of appeal and constitutes an amendment within the meaning of Article 12(4) RPBA. It directly addresses the Opposition Division's finding - of which the appellant only became aware when the decision under appeal was issued - that claim 1 as granted comprised added subject-matter. Furthermore, the amendment is directed to a combination of claims as granted. The claimed combination adds the features the omission of which resulted in added subject-matter according to the appealed decision. In view of these circumstances, the Board decided to exercise its discretion to admit the main request into the appeal proceedings.

4. Main request - Article 123(3) EPC

4.1 The respondent submits that the main request infringes Article 123(3) EPC because claim 1 of the main request extends the protection conferred by claim 1 as granted.

4.2 The protection conferred by both claim 1 as granted and claim 1 of the main request must be determined in accordance with Article 69 EPC and its protocol (G 2/88, Reasons 4).

4.3 The main point of dispute concerns the protection conferred by claim 1 as granted and, in particular, by the phrase "to determine a ratio of tissue fluid volume and blood fluid volume".

4.4 The respondent argued that this phrase limited the extent of protection to the determination of a ratio of volumes (e.g. measured in ml), and that it did not extend to the determination of indicators of such volumes.

4.5 The Board holds that this view can only result from understanding the extent of protection as being defined by the strict, literal meaning of the wording of claim 1 as granted, considered in isolation from the remainder of the patent. However, pursuant to Article 1, first sentence, of the Protocol on the Interpretation of Article 69 EPC, such an approach must not be applied.

4.6 The systems described in the patent specification may determine either a "ratio of the indicator of tissue fluid volume to the indicator of blood fluid volume" (see for example dependent claim 2, Figures 12 and 14, first sentence of paragraph [0061] as well as paragraph [0077]), or a "ratio of the value indicative of tissue fluid volume to the value indicative of blood fluid volume" (see for example dependent claim 3 as granted, Figure 13, as well as paragraphs [0059] and [0091]). The specification also teaches that use of the latter ratio requires a previous step of calculating the values indicative of tissue fluid volume and blood fluid volume based on the respective indicators (see paragraphs [0059] and [0060], Figure 13 and claim 3).

4.7 Contrary to the respondent's submission, the Board sees no reason why the dependent claims should be disregarded when determining the protection conferred under Article 123(3) EPC. On the contrary, when assessing whether an amendment extends the protection conferred by the patent, it is the totality of the claims as granted as compared with the totality of the claims after the amendment that has to be considered (G 2/88, Reasons 3.2). Therefore, even if the issue in dispute mainly concerns claim 1 as granted, the dependent claims should also be given due

consideration. In the present case, they provide meaningful context for the interpretation of claim 1.

4.8 The structure of the claims as granted, with claims 2 and 3 depending from claim 1, indicates that the ratios specified in each of claims 2 and 3 are a specific case of the ratio in claim 1. Otherwise, claim 2 would have to be understood as being directed to a system configured to determine two different ratios, in contrast to the specification, which nowhere mentions any such system.

4.9 The specification, when describing the embodiment of Figure 12, which employs the ratio of indicators, consistently refers to "the ratio of tissue fluid volume and blood fluid volume" (see paragraphs [0053]-[0057]), which is the same wording used in claim 1. This strongly supports the disputed phrase of claim 1 encompassing the determination of a ratio of indicators (claim 2) and not only of a ratio of values indicative of volumes (claim 3). This is eventually confirmed by the specification when describing the embodiment of Figure 13 in paragraph [0059], in particular its third sentence, which reads as follows: *"The ratio of tissue fluid volume to blood fluid volume may be determined based on these calculated values (530)* [i.e. the values indicative of volumes] *rather than on the values obtained with regard to the monitored indicators themselves as depicted in FIG. 12".*

4.10 It follows that the phrase of claim 1 as granted "to determine a ratio of tissue fluid volume and blood fluid volume" does not limit the extent of protection to the determination of a "ratio of the value indicative of tissue fluid volume to the value indicative of blood fluid volume". Rather, the extent

of protection also extends to the determination of a "ratio of the indicator of tissue fluid volume to the indicator of blood fluid volume".

4.11 Claim 1 of the main request calculates the "ratio of the indicator of tissue fluid volume to the indicator of blood fluid volume". For the reasons set out above, this ratio constitutes a specific ratio of the ratio which, according to claim 1 as granted, is determined by the control electronics. In other words, the amendment limits the determination of a generic ratio to the determination of a specific ratio, so the subject-matter of claim 1 of the main request corresponds to that of claim 2 as granted. In conclusion, the amendment to claim 1 does not extend the protection conferred by the claims as granted.

4.12 The same reasoning applies to claim 2 of the main request because the "ratio of the value indicative of tissue fluid volume to the value indicative of blood fluid volume" also constitutes a specific case of the ratio determined in claim 1 as granted.

4.13 It follows that the main request does not infringe Article 123(3) EPC.

5. Remittal

The appealed decision dealt only with the ground for opposition under Article 100(c) in view of Article 123(2) EPC for claim 1 as granted. As stated above, the only objection under Article 123 EPC raised by the respondent against the main request is not convincing. Hence the main request complies with the requirements of Article 123 EPC.

Both parties requested that the case be remitted for examination of substantive objections including objections of insufficient disclosure of the invention, lack of novelty and lack of inventive step. Since the decision did not deal with these objections, special reasons within the meaning of Article 11 RPBA present themselves for remitting the case to the Opposition Division for further prosecution under Article 111(1) EPC.

Order

For these reasons it is decided that:

1) The decision under appeal is set aside.

2) The case is remitted to the Opposition Division for further prosecution.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated