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Datasheet for the decision of 3 March 2020

Case Number: T 0141/15 - 3.2.02

Application Number: 08016170.6

Publication Number: 2163271

IPC: A61M1/16

Language of the proceedings: EN

Title of invention:
Method to determine the Kt/V parameter in kidney substitution treatments based on a non-linear fitting procedure

Patent Proprietor:
B. Braun Avitum AG

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 53(c)

Keyword:
Exception to patentability - therapeutic and surgical treatment (yes)

Decisions cited:
T 0245/87, T 1695/07, G 0001/04, G 0001/07

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0141/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 March 2020

Appellant: (Patent Proprietor)	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen (DE)
Representative:	Winter, Brandl, Fürniss, Hübner, Röss, Kaiser, Polte - Partnerschaft mbB Patent- und Rechtsanwaltskanzlei Alois-Steinecker-Strasse 22 85354 Freising (DE)
Respondent: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 24 November 2014 revoking European patent No. 2163271 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	M. Stern
	R. Romandini

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the Opposition Division revoking European patent No. 2 163 271. That decision had held that the subject-matter claimed lacked novelty over document WO-A-94/08641 (D1). However, it had found that the claims of the granted patent were compliant with Article 53(c) EPC.

II. Oral proceedings before the Board were held on 3 March 2020.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of the set of claims of auxiliary requests 1 to 3 filed with letter dated 27 March 2015 or auxiliary requests 4 to 7 filed with letter dated 21 June 2016.

The respondent (opponent) requested that the appeal be dismissed.

III. Claim 1 of the granted patent (**main request**) reads as follows (feature numbering in square brackets added by the Board):

"1. [1.1] A method for measuring the adequacy parameters that are achieved during a kidney substitution treatment,
- [1.2] wherein the kidney substitution treatment is provided by a machine, which has an extracorporeal blood system pumping the patient blood at a set blood flow rate through the blood chamber of a dialyzer, divided by a semi-permeable membrane into the blood chamber and a dialyzing fluid chamber, the dialyzing

fluid flows at a preset flow rate through the dialyzing fluid system of the machine and collects the waste products from the patient after flowing through the dialyzing fluid chamber of the dialyzer,
- [1.3] wherein a device able to measure continuously a kidney substitution treatment related waste product is mounted in the dialyzing fluid system of the kidney substitution treatment machine,
- [1.4] wherein the data provided by the kidney substitution treatment machine is used to measure the adequacy parameters at the end of the kidney substitution treatment,
- [1.5] wherein the data provided by the device able to measure continuously any kidney substitution treatment waste product is split in subsets to be used to determine the adequacy parameters achieved during the kidney substitution treatment with an algorithm,
- [1.6] wherein a data interface is implemented between the kidney substitution treatment machine and the measuring device in order to register machine events to be considered in the algorithm for the determination of the adequacy parameters, and
- [1.7] wherein the measuring algorithm is based on a kind of non linear fitting procedure for each of the data subsets with or without considering any kind of event happening on the dialysis machine."

IV. In claim 1 of **auxiliary request 1**, the following features have been added to the end of claim 1 of the main request:

"..., and
- wherein the machine events considered in the algorithm are blood flow change, dialysate flow change, therapy time or sequential periods."

V. In claim 1 of **auxiliary request 2**, the following features have been added to the end of claim 1 of the main request:

"..., and
- wherein the data subsets are based on periods of constant treatment parameters."

VI. In claim 1 of **auxiliary request 3**, features [1.5] to [1.7] of claim 1 of the main request have been replaced with the following wording (changes compared with claim 1 of the main request are highlighted by the Board):

"- [1.5] wherein the data provided by the device able to measure continuously any kidney substitution treatment waste product is split into a plurality of data subsets to be used to determine the adequacy parameters achieved during the kidney substitution treatment with an algorithm,
- wherein, in a period of constant treatment parameters, each of the plurality of data subsets is arranged to contain a predetermined default number of data and data subsets are generated periodically, and in a period of changing treatment parameters as a machine event happening on the dialysis machine and requiring to be considered in the algorithm for the determination of the adequacy parameters, a currently generated data subset is closed regardless of the number of data contained therein and a new data subset is forcedly started,
- [1.6] wherein a data interface is implemented between the kidney substitution treatment machine and the measuring device in order to register said machine events and to indicate if a machine event is not to be

considered in the algorithm for the determination of the adequacy parameters, and
- [1.7] wherein the measuring algorithm is based on a ~~kind of~~ non linear fitting procedure for each of the data subsets with considering a machine event, or without considering a machine event if the data interface indicates that the machine event is not to be considered ~~any kind of event happening on the dialysis machine~~."

VII. Claim 1 of **auxiliary request 4** reads as claim 1 of auxiliary request 3, except that the second paragraph of feature [1.5] has been replaced with the following:

"- wherein, in a period of constant treatment parameters, each of the plurality of data subsets is arranged to contain a number of measurements determined by splitting a measured data set into a number of pieces, and data subsets are generated periodically, and in a period of changing treatment parameters as a machine event happening on the dialysis machine and requiring to be considered in the algorithm for the determination of the adequacy parameters, a currently generated data subset is closed even if it does not yet contain the said number of measurements and a new data subset is forcedly started,"

VIII. Claim 1 of **auxiliary request 5** reads as claim 1 of auxiliary request 3, except that the second paragraph of feature [1.5] has been replaced with the following:

"- wherein, in a period of constant treatment parameters, each of the plurality of data subsets is arranged to contain a number of measurements determined by splitting a measured data set into a number of pieces, and data subsets are generated periodically,

and in a period of changing treatment parameters as a machine event happening on the dialysis machine and requiring to be considered in the algorithm for the determination of the adequacy parameters, a currently generated data subset is closed even if it does not yet contain the said number of measurements and a new data subset is forcedly started after lapse of a predetermined dead time,"

IX. Claim 1 of **auxiliary request 6** reads as claim 1 of auxiliary request 3, except that the second paragraph of feature [1.5] has been replaced with the following:

"- wherein, in a period of constant treatment parameters, each of the plurality of data subsets is arranged to contain a number of measurements determined by splitting a measured data set into a number of pieces, said number of pieces being between eight and twelve, and data subsets are generated periodically, and in a period of changing treatment parameters as a machine event happening on the dialysis machine and requiring to be considered in the algorithm for the determination of the adequacy parameters, a currently generated data subset is closed even if it does not yet contain the said number of measurements and a new data subset is forcedly started,"

X. Claim 1 of **auxiliary request 7** reads as claim 1 of auxiliary request 3, except that the second paragraph of feature [1.5] has been replaced with the following:

"- wherein, in a period of constant treatment parameters, each of the plurality of data subsets is arranged to contain a number of measurements determined by splitting a measured data set into a number of pieces, said number of pieces being between eight and

twelve, and data subsets are generated periodically, and in a period of changing treatment parameters as a machine event happening on the dialysis machine and requiring to be considered in the algorithm for the determination of the adequacy parameters, a currently generated data subset is closed even if it does not yet contain the said number of measurements and a new data subset is forcedly started after lapse of a predetermined dead time,"

XI. The arguments of the appellant that are relevant for the present decision may be summarised as follows:

The claimed invention concerned a method for measuring and determining the adequacy parameters achieved during a kidney substitution treatment (feature [1.1] of claim 1), for example Kt/V. This was the aim and intention of the invention. Moreover, the claim only contained measurement steps, but did not comprise any therapeutic or surgical steps. In particular, feature [1.2] of claim 1 merely stated the operational parameters of the dialysis machine under which the claimed measuring method took place, but did not comprise any therapeutic or surgical steps. There was, moreover, no functional link between the method steps for determining the adequacy parameters and the treatment. Furthermore, as defined in feature [1.4] of claim 1, these parameters were determined at the very end of the treatment, which made it clear that there was no feedback or control mechanism affecting the treatment based on the determination of the adequacy parameters. Following decision T 245/87, the Boards of Appeal had constantly held that a method which was only concerned with operating a device, without any functional link between the claimed method and the effects produced by the device on the body, did not qualify as a method for

treatment within the meaning of Article 53(c) EPC. The claimed method was only concerned with operating a device for determining the adequacy parameters of the treatment. Therefore, claim 1 of the main request and all the auxiliary requests complied with the requirements of Article 53(c) EPC.

XII. The arguments of the respondent that are relevant for the present decision are essentially those on which the reasons set out below are based. The respondent argued in particular that, in all the requests on file, the claimed method comprised a therapeutic and surgical step, functionally linked with the measurement step. Hence, the claimed method comprised a step excluded from patentability under Article 53(c) EPC. For this reason, claim 1 of the main request and the auxiliary requests was not allowable.

Reasons for the Decision

1. The appeal is admissible.

2. The method of claim 1 (of all requests) is addressed at a "*method for measuring the adequacy parameters that are achieved during a kidney substitution treatment*" (feature [1.1]), that is, a method for measuring parameters reflecting the adequacy of a dialysis treatment, such as Kt/V, as explained in paragraphs [0001] and [0002] of the patent (K is the effective clearance for urea, t is the treatment time and V is the urea distribution volume which matches the total body water).

3. The claimed method recites a first step (feature [1.2]), according to which "*the kidney*

substitution treatment is provided by a machine, which has an extracorporeal blood system pumping the patient blood at a set blood flow rate through the blood chamber of a dialyzer, divided by a semi-permeable membrane into the blood chamber and a dialyzing fluid chamber, the dialyzing fluid flows at a preset flow rate through the dialyzing fluid system of the machine and collects the waste products from the patient after flowing through the dialyzing fluid chamber of the dialyzer".

The appellant considered this definition to merely state the operational conditions of the dialysis machine under which the claimed measuring method takes place. According to the appellant, the latter did not comprise any therapeutic or surgical step.

The Board disagrees. The claim wording "*the kidney substitution treatment* [i.e. the dialysis treatment] *is provided...*" makes it unequivocally clear that a dialysis treatment is indeed performed. Feature [1.2] of claim 1 specifies, moreover, that the treatment is carried out by pumping the patient blood at a set blood flow rate through the blood chamber of a dialyser, the dialysing fluid collecting the waste products from the patient after flowing through the dialysing fluid chamber of the dialyser.

4. The claimed method goes on to recite various measuring and determination steps (features [1.3] to [1.7]), such as measuring "*continuously a kidney substitution treatment related waste product*" and, using this data, determining "*the adequacy parameters at the end of the kidney substitution treatment*".

5. The Board considers, therefore, that the claimed method comprises, in essence, a first step of performing dialysis treatment and a second step of measuring a parameter reflecting the adequacy of this treatment.

The step of providing dialysis to a patient enables the removal of water, solutes and toxins ("waste products") from the patient's blood. Consequently, it is a method step for treatment of the human body by therapy.

Moreover, dialysis is a blood manipulation process involving the continuous removal of blood from the patient, its subsequent flowing through a circulating line of an extracorporeal circuit and its re-delivery to the patient, which, in accordance with T 1695/07 (points 8 to 12), is considered to be a treatment of the human body by surgery.

6. According to the established case law of the Boards of Appeal, a multi-step method falls under the exception clause of Article 53(c) EPC if it includes at least one feature that constitutes a method step for treatment of the human body by therapy or surgery (G 1/04, point 6.2.1; G 1/07, point 3.2.5).

In view of the above, this is the case for the method of claim 1. The therapeutic and surgical nature of the claimed method is not changed by the fact that claim 1 is formally addressed at a "*method for measuring the adequacy parameters that are achieved during a kidney substitution treatment*". This opening line in claim 1 is essentially a summary of the measuring steps defined in the claim. It may be seen merely as a label for the claimed method. It certainly does not detract from the fact that the claimed subject-matter is a multi-step method comprising, apart from the parameter-measuring

step, the mentioned therapeutic and surgical step. The possible intention or aim of the invention mentioned by the appellant - determining parameters reflecting the adequacy of a dialysis treatment - is not relevant for establishing the subject-matter of the claim.

7. The appellant argued, referring to decision T 245/87, that the Boards of Appeal had constantly held that a method which was only concerned with operating a device without any functional link between the claimed method and the effects produced by the device on the body did not qualify as a method for treatment within the meaning of Article 53(c) EPC (see also G 1/07, point 4.3.2). In the present case there was no functional link between the method steps for determining the adequacy parameters and the treatment. As defined in feature [1.4], these parameters were determined at the very end of the treatment, which made it clear that there was no feedback or control mechanism affecting the treatment based on the determination of the adequacy parameters. Therefore, the claimed method was only concerned with operating a device for determining the adequacy parameters of the treatment.

The Board disagrees with these conclusions.

The case underlying T 245/87 concerns a method for measuring the flow rate of a small fluid volume inside a duct. According to the description of the application in that case, the method may be applied to an implantable dosage apparatus delivering a medicament, such as insulin, to a patient's body. Although the claim in that case could be interpreted as encompassing an embodiment in which a medicament such as insulin is implicitly delivered to the patient, it was decided in

T 245/87 (point 3) that there was no functional link between the claimed method and the effects produced by the device on the body and that the claimed method was merely directed to operating a device.

In the present case, however, the determination of the adequacy parameters is carried out by processing data gathered from continuous measurements of the waste products which are directly produced by the dialysis treatment (features [1.3] and [1.4]). In contrast to the case underlying T 245/87, the claim defines a continuous measurement of the effects produced by the therapeutic and surgical treatment. Therefore, the measurement step and the dialysis treatment step are inextricably linked with each other, establishing a functional link between the claimed measurement steps and the effects of the dialysis treatment on the patient's body. It is thus of no relevance that the claim does not contain a feedback mechanism between the adequacy parameters and the treatment, as argued by the appellant. In the present case, the claimed method is concerned not just with operating a device for determining the adequacy parameters of the treatment, but also with performing the treatment and measuring its effects for determining the parameters.

8. The Board thus concludes that claim 1 (of all the requests) defines a method for treatment of the human body by therapy and surgery which is excluded from patentability under Article 53(c) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated