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Datasheet for the decision of 31 March 2016

Case Number: T 0821/12 - 3.2.02

Application Number: 06025617.9

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IPC: A61B5/028

Language of the proceedings: EN

Title of invention:
Dilution apparatus and computer program

Patent Proprietor:
IPRM Intellectual Property Rights Management AG

Opponent:
Pulsion Medical Systems SE

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
T 0158/97, T 0258/97, T 0641/00, T 1265/09

Catchword:

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Case Number: T 0821/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 31 March 2016

Appellant: (Opponent)	Pulsion Medical Systems SE Joseph-Wild-Strasse 20 81829 München (DE)
Representative:	Ettmayr, Andreas KEHL, ASCHERL, LIEBHOFF & ETTMAYR Patentanwälte Emil-Riedel-Strasse 18 80538 München (DE)
Respondent: (Patent Proprietor)	IPRM Intellectual Property Rights Management AG c/o Dr. Hans Durrer Gotthardstrasse 20 6304 Zug (CH)
Representative:	Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Postfach 31 02 60 80102 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 January 2012 rejecting the opposition filed against European patent No. 1797820 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	M. Stern

Summary of Facts and Submissions

I. On 19 January 2012 the Opposition Division posted its interlocutory decision to reject the opposition against European patent No. 1797820.

II. An appeal was lodged against this decision by the opponent by notice received on 15 March 2012, with the appeal fee having been paid on the preceding day. The statement setting out the grounds of appeal was received on 17 May 2012.

III. By communication of 8 December 2015, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

IV. Oral proceedings were held on 31 March 2016.

The final requests of the parties were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed, or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of the auxiliary request filed with letter dated 8 October 2013.

V. The following documents are of importance for the present decision:

D1: US-A-2005/0267378
D2: US-A-5526817

D3: P.D. Wagner: "Vascular transit times in the lung", J. Appl. Physiol. 79 (1995), 380-381

D4: W.H. Noble et al.: "Reappraisal of extravascular lung thermal volume as a measure of pulmonary edema", J. Appl. Physiol.: Respirat. Environ. Exercise Physiol. 48(1) (1980), 120-129

D5: E.A. von Reth and J.M. Bogaard: "Comparison of a two-compartment model and distributed models for indicator dilution studies", Med. Biol. Eng. & Comp. 21 (1983), 453-459.

VI. Claims 1 and 10 of the patent as granted read:

"1. Apparatus for determining a patient's circulatory filling status, adapted to provide a dilution curve and to derive the ratio between the patient's global end-diastolic volume (GEDV) and the patient's intrathoracic thermal volume (ITTV) from the dilution curve by means of the degree of asymmetry of the shape of the dilution curve."

"10. Computer program for determining a patient's circulatory filling status, having instructions adapted to carry out the steps:
generating a dilution curve on basis of provided measurement data of dilution versus time,

- determining the patient's circulatory filling status on basis of the ratio between the patient's global end-diastolic volume (GEDV) and the patient's intrathoracic thermal volume (ITTV),

- determining the degree of asymmetry of the shape of the dilution curve, and

● determining the ratio between the patient’s global end-diastolic volume (GEDV) and the patient’s intrathoracic thermal volume (ITTV) by means of the degree of asymmetry of the shape of the dilution curve when run on a computer."

Claims 2 to 9 and 11 to 18 are dependent claims.

VII. The appellant's arguments are summarised as follows:

The length of the downslope time DST was a measure of the skewness of a dilution curve which was typically an asymmetrical curve (as known from D3, page 380, column 2, item 3) and whose skewness could be well estimated by the length of DST (as known from D5, page 455, Figure 3, wherein DST corresponded to [the skewness parameter] λ). In the specification of the contested patent, the degree of asymmetry was not unambiguously defined. The skilled person would understand from the specification of the contested patent that any value quantifying the asymmetry of the dilution curve could be considered a degree of asymmetry. Such understanding was consistent with the skilled person's general knowledge. The skilled person would clearly understand that various parameters of a given dilution curve or derived therefrom could serve as a measure for its degree of asymmetry. In the case of the thermodilution curve, this could include DST, MDT etc. and mathematical transformants of these. As the description provided a spectrum of possibilities with respect to interpreting the feature "degree of asymmetry of the thermodilution curve", it was entirely logical for the skilled person to subsume all values and determinants of such curves known from the state of the art and transformants thereof under that feature as far as they varied with skewness (asymmetry). As DST quite clearly

was such a measure of the degree of asymmetry, it fell under the scope of claim 1.

Known derivations of the parameters GEDV and ITTV making use of the inherently asymmetrical dilution curve and terms such as MTT and DST, also fell under the broad claim (as to be seen from Newman et al., Circulation, Vol. IV, p. 735-746; 1951 as the underlying reference, cited in D2). The skilled person knew that skewness was a measure of the degree of asymmetry of a distribution. Hence, the derivation of GEDV and ITTV by utilization of parameters, which determined the skewness of the thermodilution curve, e.g. a combination of MTT and DST, as disclosed in D2, clearly fell within the ambit of claim 1.

The thermodilution curve became more asymmetric (skewed) with increasing DST, as exemplified by D5. Although neither Newman nor Noble et al. specifically used the term "DST", it was clear that it referred to the down slope part of the dilution curve. By using DST, as disclosed in D2, the degree of asymmetry of the curve was assessed, since the length of DST was a direct indicator of the skewness at least of the descending limb of the dilution curve. At the same time the parameter MTT, as disclosed in D2, was taking account of the whole of the curve. Hence, by utilizing DST and MTT as determinants in D2, GEDV and ITTV were calculated by means of the degree of asymmetry of the thermodilution curve. Dl also disclosed the determination of both ITTV and GEDV ([0006], [0007]), by means of MTT and DST, utilizing a computer system. Since D1 and D2 both disclosed the determination of DST and MTT, the disclosed apparatus were also adapted to derive the ratio between GEDV and ITTV by means of the degree of asymmetry and were thus novelty-destroying.

Moreover, from claim 21 of D1 it was clear that lung volume (PTV) was the main parameter responsible for the asymmetry of the dilution curve. The determination of GDTV according to the equation of claim 21 was always dependent on the asymmetry of the curve. The equation in paragraph [0028] of D1 could be regarded as a disclosure of the claimed derivation of the ratio between GEDV and ITTV.

According to established case law, an invention which consists of a combination of technical and non-technical features has to be assessed with respect to inventive step by taking account of all those features which contribute to the technical character of the claimed subject-matter. Features making no such contribution, however, cannot support the presence of an inventive step (T 1265/09).

All purely technical features of claim 1 were known in combination from D2. The difference between D2 and claim 1 was thus based on the algorithm employed, which as such constituted a non-technical feature. According to T 258/97, such an abstract algorithm could only be relevant if a technical effect was causally linked to the algorithm. However, the claimed formation of a ratio between GEDV and ITTV provided neither additional information nor a technical effect. It was, at most, a mere change of presentation, which was not to be taken into account when assessing inventive step, as ruled in T 641/00. This kind of change of presentation or mathematical rearrangement was anyhow part of the general knowledge of the skilled person and therefore obvious. Quite clearly, a mere change in representation could not be considered as conferring the proposed technical effect. Hence, the skilled person would treat

this mathematical transformation as a technically non-functional modification, which was irrelevant to inventive step according to T 158/97.

From D3 (page 380, middle of right-hand column) and D4 (page 120, middle of right-hand column), the skilled person knew that both MDT and MTT, were well-suited parameters taking into account the asymmetry of the dilution curve (as was also described in paragraphs [0052] to [0057] of the patent in suit). When starting from D1 or D2 and pursuing the aim of increasing the accuracy of determining the circulatory fill status as mentioned in paragraph [0026] of the patent, it was within the skilled person's general knowledge as evidenced by D3 and D4 that MDT was an additional valuable parameter. This rendered obvious the subject-matter of claim 4 and hence, a fortiori, that of claim 1 of the main request.

VIII. The respondent's arguments are essentially those on which the following reasons for this decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Novelty – main request

2.1 Document D1

D1 discloses an apparatus for determining a patient's circulatory filling status (paragraph [0051]), adapted to provide a dilution curve (Figure 3).

D1 further discloses the determination of the down slope time (DST) of the dilution curve (claim 12). As can be seen from Figure 3, DST is a parameter derived from exclusively the descending part of the dilution curve (which is generally asymmetric, as correctly observed by the appellant).

Contrary to the appellant's view, DST cannot be regarded as an indication of a "degree of asymmetry of the shape of the dilution curve" as claimed. It is also not agreed that the term "degree of asymmetry of the shape of the dilution curve" is not unambiguously defined in the patent specification, and that it is unclear how this entity is to be determined. Paragraphs [0062] and [0063] and claim 6 of the patent as granted provide an example based on the ratio of the slopes of the rising and the descending parts of the dilution curve. From paragraphs [0030] to [0032] and claim 2 it is clear that it is also possible to take into account the ratio between the median transit time (MDT) and the mean transit time (MTT) for that purpose.

It is certainly true that DST may have an influence on the asymmetry of the dilution curve, as conceded by the respondent. For instance, an increasing DST may result in a more asymmetric dilution curve. But this is only so if the rising slope of the curve remains constant. As correctly pointed out by the respondent, this is not necessarily the case. Certain physiological conditions may, for instance, result in the dilution curve being merely compressed or expanded in time, resulting in a change of DST without the degree of asymmetry being altered. The term "degree of asymmetry" implies that both the rising and the descending part of the dilution curve are taken into account and put in relation to each other. Accordingly, DST alone cannot be regarded

as a measure of the degree of asymmetry, since it characterises the descending part of the dilution curve only.

Referring to claim 21 of D1, the appellant argued that that lung volume (PTV) was the main parameter responsible for the asymmetry of the dilution curve, and that the determination of the global end diastolic volume (GEDV) according to the equation of claim 21 was always dependent on the asymmetry of the curve. This does not, however, imply that the degree of asymmetry is actually determined.

Since D1 already fails to disclose a determination of the "degree of asymmetry of the shape of the dilution curve", it does also not anticipate that the apparatus of D1 is adapted to "derive the ratio between the patient’s global end diastolic volume (GEDV) and the patient’s intrathoracic thermal volume (ITTV) from the dilution curve, **by means of** the degree of asymmetry of the shape of the dilution curve" [emphasis added]. The fact that it is (undisputedly) disclosed in D1 that both parameters, GEDV and ITTV, are determined does not imply that a ratio thereof is derived "by means of" the degree of asymmetry. The Board also does not follow the appellant's argument that the equation in paragraph [0028], a term of which comprises the difference between ITTV and GEDV, can be regarded as a disclosure of the ratio between these parameters.

2.2 Document D2

D2 (the inventors of which are also among those of D1) does not disclose the above-mentioned features either.

The appellant's line of arguments is essentially similar to that presented with respect to D1. Regarding D2, it was additionally argued in detail that this document disclosed that MTT, which took account of the whole of the dilution curve, was determined simultaneously with DST, and that by utilising DST and MTT as determinants, GEDV and ITTV were calculated by means of the degree of asymmetry of the dilution curve. However, in view of the (hypothetical) examples of a perfectly symmetric and an extremely asymmetric curve, both yielding identical values of DST and MTT, as presented by the respondent in its submission of 25 February 2016, this argument is not convincing. The fact that a perfectly symmetric dilution curve is unrealistic (as correctly observed by the appellant) is not decisive in this regard: it is equally conceivable that identical values of both parameters can also be obtained for an extremely asymmetric and a less asymmetric curve. Even though MTT is in fact calculated on the basis of the entire dilution curve and DST on the basis of its descending branch, it cannot be seen how the simultaneous determination of both values can be regarded as a (direct an unambiguous) disclosure of a determination of the degree of asymmetry of the shape of the dilution curve. The Board is also not able to derive from the journal article by Newman et al. (cited in paragraph [0009] of the patent in suit) that, as alleged by the appellant, "terms such as MTT and DST, also fall under this broad claim". Figure 3 of D5 only depicts the relationship between the skewness parameter λ of a dilution curve (calculated on the basis of a local density random walk distribution) and the absolute ratio of the slopes at the inflection points in the ascending and descending limbs of the curve. This does not imply that λ corresponds to DST, as alleged by the appellant.

2.3 Accordingly, the subject-matter of claim 1 of the main request is novel within the meaning of Article 54 EPC. The same applies to claim 10, which comprises the distinguishing features of claim 1 in terms of method steps of a computer program.

3. Inventive step – main request

3.1 Document D1 (cited in paragraph [0025] of the patent is suit) may be regarded as the closest prior art. As mentioned above, it discloses an apparatus for determining a patient's circulatory filling status adapted to provide a dilution curve, from which the subject-matter of claim 1 is distinguished in that the apparatus is adapted to derive the ratio between GEDV and ITTV from the dilution curve by means of the degree of asymmetry of the shape of the dilution curve.

3.2 As mentioned in paragraph [0036] of the patent in suit, the technical effect underlying the distinguishing features is that, by means of the degree of asymmetry of the shape of the dilution curve, the ratio between GEDV and ITTV is less affected by temperature drift and blood recirculation.

3.3 Accordingly, the objective technical problem is to provide an apparatus allowing a more accurate determination of the patient's circulatory fill status, as stated in paragraph [0026] of the patent in suit.

3.4 The appellant argued that the distinguishing feature was a "mere change in representation" of the two numbers GEDV and ITTV that could not be considered as conferring the proposed technical effect. Such a mathematical transformation was a "technically non-

functional modification, which is irrelevant to inventive step", and was not to be taken into account for the assessment of inventiveness according to T 158/97. However, in the case underlying that decision, the distinguishing feature had no technical function at all, and in fact was even regarded as technically disadvantageous. In the present case, however, the distinguishing features do have the above-mentioned technical effect, thus contributing to the technical character of the invention, and may not be disregarded. For that reason, the appellant's reference to T 641/00 and T 1265/09 is also not appropriate with respect to the present case.

For the same reason, the Board does not accept the appellant's argument that the distinguishing features are only "based on the algorithm employed, which as such constitutes a non-technical feature", thus "not providing a contribution to the solution of a technical problem", as ruled in T 258/97.

3.5 The appellant further referred to point 3) in the right-hand column of page 380 of D3. However, this passage only states what is generally known, namely that dilution curves are markedly skewed and that MDT may be as little as 60% of MTT. This cannot be seen as a hint to derive the ratio between GEDV and ITTV by means of the degree of asymmetry. The same applies to the cited reference to the middle of the right-hand column of page 120 of D4, which merely states that the extravascular thermal volume of the lung can be determined on the basis of MDT.

3.6 Figure 3 at page 455 of D5 was cited by the appellant as evidence for the estimation of skewness of the dilution curve by the length of DST. As already

mentioned above, Figure 3 only depicts the relationship between the skewness parameter λ of a dilution curve and the absolute ratio of the slopes at the inflection points in the ascending and descending limbs of the curve. There is no hint whatsoever towards deriving the ratio between GEDV and ITTV on that basis.

3.7 D1 deals with the problem of determining the intrathoracic blood volume by thermodilution for patients suffering from special kinds of disorder (paragraph [0012]). D2 aims at determining a patient's circulatory fill status without dye dilution, using only thermo-dilution (column 2, lines 21 to 24). These problems are entirely unrelated to the above-mentioned technical effects underlying the distinguishing features of claim 1.

3.8 Since none of the cited documents gives a hint to these distinguishing features or the underlying technical effects, they do not render obvious the subject-matter of claim 1. Accordingly, the subject-matter of claim 1 of the main request is based on an inventive step within the meaning of Article 56 EPC. The same applies to claim 10, which comprises the distinguishing features of claim 1 in terms of method steps of a computer program.

4. As confirmed at the end of the oral proceedings, the appellant did not have any further objections to the main request. It follows that the cited grounds of opposition under Article 100(a) EPC do not prejudice the maintenance of the patent as granted.

5. Under these circumstances, it is not necessary for the Board to deal with the auxiliary request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated