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Datasheet for the decision of 25 March 2025

Case Number: T 0397/23 - 3.2.02

Application Number: 14199419.4

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Language of the proceedings: EN

Title of invention:
Monitoring and displaying a patient's status

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
Pulsion Medical Systems SE

Relevant legal provisions:
EPC Art. 83, 113(2)
EPC R. 103(1)(a), 111(2)

Keyword:
Sufficiency of disclosure - (all requests - no)
Reimbursement of appeal fee - appealed decision sufficiently reasoned (yes) - violation of the right to be heard (no) - (no)

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Case Number: T 0397/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 March 2025

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
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Appellant: (Opponent)	Pulsion Medical Systems SE Hans-Riedl-Str. 21 85622 Feldkirchen (DE)
Representative:	Kehl, Ascherl, Liebhoff & Ettmayr Patentanwälte Partnerschaft mbB Emil-Riedel-Straße 18 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 December 2022 concerning maintenance of European patent No. 2881034 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the interlocutory decision of the opposition division to maintain the contested patent as amended according to the request then on file as auxiliary request 3.

II. In its decision, the opposition division had found, *inter alia*, that the patent disclosed the invention to which it related in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (see Reasons 2.2 and 5.3).

III. The **appellant-opponent** requested that the decision under appeal be set aside, that the patent be revoked and that its appeal fee be refunded.

IV. The **appellant-patent proprietor** requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, that it be maintained as amended on the basis of the claims of one of auxiliary requests 1 to 7 filed with its reply to the opponent's statement of grounds of appeal.

V. Oral proceedings were held before the Board on 25 March 2025.

VI. The following documents are relevant to this decision:

D5 US 2004/0249297 A1

D7 D. A. Reuter *et al.*, "Einschätzung der Volumenreagibilität beim beatmeten Patienten", Anaesthesist 52, 2003, 1005-1013

D11 "Frank-Starling Mechanism", CV Physiology

VII. Claim 1 of the **main request** (patent as granted) reads as follows (with the feature numbering used in the decision under appeal):

F1 "*A system (101) for providing a physiological representation of a patient, comprising:*

F2 *a sensor (110) configured to monitor a physiological parameter of a patient corresponding to an organ of the patient and provide an output signal corresponding to the monitored physiological parameter;*

F3 *a processing unit (106) and*

F4 *a display device (100); wherein*

F5 *the organ comprises the heart of the patient; and*

F6 *the processing unit is configured to cause the display device to display the organ,*

F7 *and to display a shape change of the organ or an animation of the organ based on the output signal;* ***characterized in that***

F8 *the processing unit is further configured to cause the display device (100) to display a stroke volume variation starling curve (2102) with an indicator (2106) representing a stroke volume variation value (2104), the indicator moving along the stroke volume variation starling curve corresponding to the stroke volume variation value.*"

VIII. Claim 1 of each of **auxiliary requests 1 to 7** is based on claim 1 as granted, except that, *inter alia*:

(a) in feature F8 of **auxiliary requests 1 to 3**, the punctuation mark ":" has been inserted after the words "configured to"

(b) in feature F8 of **auxiliary requests 4 to 7**, the following amendment has been made (highlighted by the Board), and the punctuation mark ":" has been inserted after the words "configured to" in auxiliary requests 5 to 7:

"*the processing unit is further configured to cause the display device (100) to display a general stroke volume variation starling curve (2102) [...]*"

IX. The **opponent's arguments**, where relevant to the present decision, can be summarised as follows.

Insufficiency of disclosure

The invention as claimed in all of the claim requests on file was insufficiently disclosed. Even using common general knowledge, a person skilled in the art would not be able to implement feature F8 since it was completely obscure.

A "stroke volume variation starling curve" was not known outside the contested patent and the patent did not disclose what this curve was supposed to be and what was needed to be implemented in order to provide and display it. Moreover, the patent did not disclose how to implement an indicator which moved along this

curve and "correspond[ed]" to a stroke volume variation (SVV) value. Paragraph [0058] and Figures 22 to 24, which were the only parts of the patent specification relating to this curve and indicator, shed no light on these issues. Assuming that the "stroke volume variation starling curve" was a curve with a shape similar to the shape of a Frank-Starling curve - and this assumption was already questionable in the absence of any such disclosure in the patent - did not help, since a Frank-Starling curve showed the variations in stroke volume (SV), not SVV. Moreover, the shape of a Frank-Starling curve, and thus the steepness of its various portions, was highly dependent on the individual patient and their current physical condition, as shown by, for example, D5 (Figure 1), D7 (Figure 1) and D11 (page 3). It was therefore completely unclear how, in these circumstances, an indicator representing an SVV value could be represented on such a curve, especially since Figures 22 to 24 did not show any coordinate system or other markings that would allow the position of the indicator 2106 to be correlated with any actual values.

Request for reimbursement of the appeal fee

Several aspects of the decision under appeal were not sufficiently reasoned as required by Rule 111(2) EPC.

Concerning the question of whether the subject-matter of the claims of the request then on file as auxiliary request 3 was inventive (see Reasons 5.2), the opposition division merely stated that its distinguishing features were technical. However, the opposition division did not elaborate as to whether or not these features were obvious in view of the prior art.

Concerning the question of whether the amendments based on the description were clear (see Reasons 4.1), the opposition division stated that the terms "time-lapse graph" and "reference point" "must" be interpreted to have a specific meaning, but did not indicate the considerations on which this finding was based.

As a consequence, the opponent was not in a position to understand objectively whether or not the decision under appeal was justified on these issues, and why the opponent's submissions had not been found convincing, with the result that the opponent's right to be heard had been violated, in breach of Article 113(1) EPC. This justified the reimbursement of the opponent's appeal fee under Rule 103(1)(a) EPC.

X. The **patent proprietor's arguments**, where relevant to the present decision, can be summarised as follows.

Insufficiency of disclosure

Feature F8 was sufficiently disclosed in the contested patent and a person skilled in the art would be able to carry out the invention as claimed in all of the claim requests on file without undue burden, using common general knowledge and the information provided in the patent.

Irrespective of whether the expression "stroke volume variation starling curve" had a generally accepted meaning in the art, this curve and the corresponding moving indicator were well defined in paragraph [0058] and Figures 22 to 24 of the patent.

The person skilled in the art would immediately understand from the patent specification that the "stroke volume variation starling curve" could only be a typical, schematic Starling curve - which was well known in the art as a curve showing the variation of stroke volume (SV) with end-diastolic volume - on which an indicator for a stroke volume variation (SVV) value was placed. It was common general knowledge that high SVV values were located on the left-hand, steeper part of the Starling curve, while low SVV values were located on the right-hand, flatter part (see, for example, D7, Figure 3). In line with this common general knowledge, the person skilled in the art was instructed by paragraph [0058] and the figures to place the indicator 2106 on the right-hand, flat portion of the curve for lower SVV values such as 5%, as shown in Figure 22 (which represented a good patient condition and was referred to as being the "target range" in paragraph [0058]); in the middle, transitioning portion of the curve for intermediate SVV values such as 14%, as shown in Figure 23 (which represented a weak patient condition and was referred to as being the "warning range" in paragraph [0058]); and in the left-hand, steep portion of the curve for higher SVV values such as 35%, as shown in Figure 24 (which represented a poor patient condition and was referred to as being the "alarm range" in paragraph [0058]).

In any event, the person skilled in the art was easily able to reproduce the curved line shown in Figures 22 to 24 on a screen of a patient monitoring system and place an indicator on this curve for each measured SVV value by interpolation of the example SVV values shown in these figures.

It was irrelevant that the Starling curve might vary depending on the patient's condition or differ from patient to patient, since its general shape still typically remained the same, as shown, for example, in Figure 1 of D5. Furthermore, the fact that the indicator might not be placed at the clinically correct location on the Starling curve for some patients did not render the claimed invention insufficiently disclosed, since it did not prevent the person skilled in the art from displaying the curve and placing an indicator on it as required by feature F8.

Reasons for the Decision

1. Subject-matter of the contested patent

1.1 The contested patent relates to a system for providing a physiological representation of a patient and to a computer-readable medium storing a corresponding program, as defined in independent claims 1 and 4 as granted, respectively. The system is intended to provide a patient monitoring user interface which allows clinicians to monitor and determine a patient's physiological status more accurately, intuitively and easily (paragraph [0008]).

1.2 The claimed system comprises a sensor configured to monitor a physiological parameter of a patient corresponding to an organ of the patient and to provide an output signal corresponding to the monitored physiological parameter, a processing unit and a display device. Claim 1 further specifies that the organ comprises the heart of the patient.

1.3 According to feature F8 of claim 1, the processing unit is "configured to cause the display device to display a

stroke volume variation starling curve (2102) with an indicator (2106) representing a stroke volume variation value (2104), the indicator moving along the stroke volume variation starling curve corresponding to the stroke volume variation value".

The only passage of the description of the patent referring to this curve and indicator is paragraph [0058], which reads as follows:

"*[0058] In another embodiment, the screen includes a stroke volume variation (SVV) starling curve 2102 with an indicator 2106 representing a SW value 2104 as shown in FIGS. 22-24. The indicator 2106 can have a first color, such as green, corresponding to the SW value 2104 being within a target range as shown in FIG. 22. The indicator 2106 can have a second color, such as yellow, corresponding to the SW value 2104 being within a warning range as shown in FIG. 23. The indicator 1016 can have a third color, such as red corresponding to the SVV value 2104 being within an alarm range as shown in FIG. 24. Furthermore, the indicator 2106 can move along the curve 1014 corresponding to the SW value 2104 as shown in FIGS. 22-24.*"

The parts of Figures 22 to 24 that are cited in this paragraph are reproduced below:

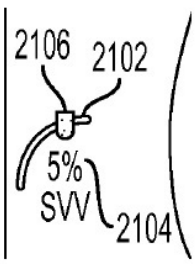

FIG. 22

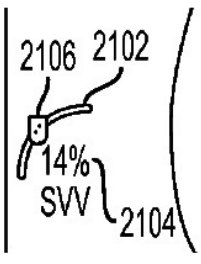

FIG. 23

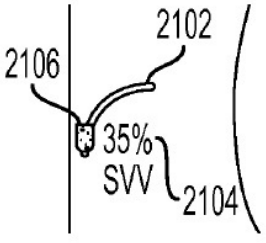

FIG. 24

2. Insufficiency of disclosure

2.1 Contrary to the proprietor's view, the invention as claimed is not disclosed in the contested patent in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2.2 As argued by the opponent, the expression "stroke volume variation starling curve" in feature F8 has no known and recognised meaning in the art, and neither claim 1 as a whole nor paragraph [0058] and Figures 22 to 24, which are the only parts of the patent specification relating to feature F8, shed any light on the nature of the curve defined by this expression.

While it is common ground that the person skilled in the art would be familiar with the "Starling curve", also known as the "Frank-Starling curve", it is also common ground that this known curve describes the variations in stroke volume (SV) with left ventricular end diastolic volume. However, since stroke volume variation (SVV) is also a well-known, clinically relevant parameter, the person skilled in the art would not construe the terms "stroke volume" and "variation" in isolation from each other and would not understand, as argued by the proprietor, the "stroke volume variation starling curve" as merely referring to a curve showing the variation in SV, i.e. to the Starling curve itself.

The proprietor further argued that the person skilled in the art would understand from the patent specification, in particular from Figures 22 to 24 which show such a curve 2102 (see point 1.3 above), that the "stroke volume variation starling curve" could

only be a typical, schematic Starling curve on which an indicator for a SVV value is placed.

The Board is not convinced by this argument. Feature F8 does not simply refer to a "starling curve", and the claimed indicator representing an SVV value is distinct from the curve itself. The person skilled in the art would therefore understand that the claimed curve itself is more than a mere representation of a Starling curve, even a schematic one. However, the extent to which the former differs from the latter is not disclosed in the patent and therefore remains obscure.

For this reason alone, the person skilled in the art would not be able to implement feature F8 in practice.

2.3 Furthermore, even assuming that the person skilled in the art did understand the "stroke volume variation starling curve" as referring to a schematic representation of a Starling curve, such as the quarter-circle shaped curve 2102 shown in Figures 22 to 24, the person skilled in the art would still be left completely in the dark as to how to represent an SVV value on a graphical curve that schematically shows the variations of SV, not SVV.

As argued by the opponent, this issue is not addressed at all in paragraph [0058], and Figures 22 to 24 merely show three particular positions of the indicator for three particular SVV values, i.e. 5%, 14% and 35%. There is no scale or other markings on the figures that would allow the position of the indicator 2106 to be correlated with the SVV value to which it corresponds. Moreover, since these figures are only schematic, the proprietor's argument that the person skilled in the art would understand from the patent that the claimed

indicator representing a particular SVV value according to feature F8 is to be placed on the (schematic) curve merely by interpolation of the three SVV values shown in Figures 22 to 24 is speculative and unconvincing.

The further argument of the proprietor that the person skilled in the art would in any case know that high SVV values are to be indicated on the left-hand, steeper part of the Starling curve, while low SVV values are to be indicated on the right-hand, flatter part, is not convincing either. While this might generally be true for a given patient, as shown in D7 (Figure 3) for example, the person skilled in the art would also be aware that, as further argued by the opponent, the shape of the Starling curve is highly dependent on the patient and their physical condition, as shown in D5 (Figure 1), D7 (Figure 1) and D11 (figure at the top of page 3). Consequently, according to the above-mentioned relationship between SVV and the steepness of the Starling curve, a given SVV value could be associated with different positions along the displayed curve for different patients, or even for a given patient at two different times. This is especially the case as the curve is a schematic curve that is not specific to a particular patient or patient's physical state. Furthermore, as also argued by the opponent, the leftmost part of the Starling curve has a relatively linear shape and thus a relatively uniform steepness. It is therefore unclear where along the curve an SVV value corresponding, in principle, to this steepness can be placed.

Therefore, even under the above assumption, the person skilled in the art would not be able, even using common general knowledge, to configure the processing unit to display with the curve "an indicator representing a

stroke volume variation value, the indicator moving along the stroke volume variation starling curve corresponding to the stroke volume variation value", as further required by feature F8. In these circumstances, the question of whether the indicator would be displayed at a clinically relevant position along the curve does not even arise.

2.4 It follows from the foregoing that, contrary to the proprietor's view, the person skilled in the art would not be able to carry out feature F8, even using common general knowledge and the (little) information contained in the patent.

2.5 The invention as claimed in the main request and auxiliary requests 1 to 3, in which claim 1 in each case includes feature F8 *verbatim*, is therefore not sufficiently disclosed.

2.6 Auxiliary requests 4 to 7 contain an amended feature F8 that refers to a "general stroke volume variation starling curve"(emphasis added by the Board). However, the addition of the word "general" cannot overcome the lack of sufficiency of disclosure found above. Auxiliary requests 4 to 7 therefore suffer from the same deficiency as the main request and auxiliary requests 1 to 3. This was not disputed by the patent proprietor at the oral proceedings before the Board.

3. In the absence of any request meeting the requirements of the EPC, the patent must therefore be revoked (Article 101(3)(b) EPC).

4. The opponent's request for reimbursement of the appeal fee

The opponent requested reimbursement of its appeal fee on the grounds that the opposition division had allegedly committed substantial procedural violations.

At the oral proceedings before the Board, the opponent did not comment further on this issue; it merely referred to its written submissions. The Board therefore sees no reason to depart from its preliminary view as set out in its communication under Article 15(1) RPBA (see point 6).

As stated therein, the Board does not consider any substantial procedural violations to have occurred. The last paragraph of point 5.2 of the Reasons of the decision under appeal, although arguably not ideally worded, is sufficiently detailed to enable a reader to understand the reasoning behind the opposition division's conclusion that features F9 to F11 rendered the subject-matter of claim 1 of auxiliary request 3 inventive over D2. As regards the assessment of clarity in the last paragraph of point 4.1 of the Reasons, the term "must" is understood to refer to the way in which the person skilled in the art would understand the contested features. The opposition division's observations in this respect expressly deal with the opponent's argument summarised two paragraphs above. Reimbursement of the opponent's appeal fee is therefore not justified.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

3. The request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated