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Datasheet for the decision
of 11 November 2014

Case Number: T 1339/11 - 3.4.03
Application Number: 07117969.1
Publication Number: 1909246
IPC: G09B23/28, G09B23/30,
     G09B23/32, G09B23/34
Language of the proceedings: EN

Title of invention:
Surgical console operable to simulate surgical procedures

Applicant:
Novartis AG

Headword:

Relevant legal provisions:
EPC 1973 Art. 56

Keyword:
Inventive step (yes)

Decisions cited:

Catchword:
Case Number: T 1339/11 - 3.4.03

DECISION
of Technical Board of Appeal 3.4.03
of 11 November 2014

Appellant: Novartis AG
(Applicant) Lichtstrasse 35
4056 Basel (CH)

Representative: Hanna, Peter William Derek
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted on 1 February 2011 refusing European patent application No. 07117969.1 pursuant to Article 97(2) EPC.

Composition of the Board:
Chairman G. Eliasson
Members: R. Bekkering
T. Karamanli
Summary of Facts and Submissions

I. The appeal is against the refusal of application No. 07 117 969 for lack of an inventive step, Article 56 EPC, over documents:

D1: EP 1 455 324 A

C1: US 5 455 766 A.

II. The appellant requested with the statement setting out the grounds of appeal that the decision under appeal be set aside and a patent be granted on the basis of the following documents as a main request:

Description: Pages 1 and 2 filed with letter of 14 January 2009; Pages 3 to 19 as originally filed;

Claims: Nos. 1 to 16 of the main request filed with letter of 21 October 2010;

Drawings: Sheets 1/4 to 4/4 as originally filed.

Alternatively, the grant of a patent was requested based on the claims according to the first or second auxiliary request, both filed with letter of 21 October 2010, or based on the claims according to the third auxiliary request submitted during the oral proceedings before the examining division.

III. Claims 1 according to the appellant's main request reads as follows:
"A surgical console (10, 100) operably useable in both actual surgical procedures and simulated surgical procedures, comprising:
a processing module (32) operable to direct operations of and receive inputs from peripheral devices (14) operably coupled to the surgical console, wherein the peripheral devices comprise surgical instruments;
at least one memory device (24, 36, 38, 40) operably coupled to the processing module; and
a user interface (12, 17, 18, 20, 115), characterized in that the at least one memory device is operable to store a simulated training surgical procedure and multimedia content,
and in that the user interface is adapted to permit the user to initialize the surgical console for a training surgical procedure and select the training surgical procedure to be simulated;
and in that the processing module is adapted to perform the simulation and evaluation [sic] the operator’s performance of the simulated training surgical procedure by providing feedback via the user interface informing the user of differences between his or her actual performance of the training surgical procedure and a desired performance."

Claim 10 reads:

"A computer-implemented method (400) for operating a surgical console (10, 100) operably useable in actual surgical procedures and to simulate a training surgical procedure, comprising the steps of:
interfacing (402) the surgical console with various peripheral devices, wherein the peripheral devices comprise surgical training instruments and simulation modules; characterized by
storing a simulated training surgical procedure and multimedia content in a memory; permitting a user to initialize (406) the surgical console for a simulated training surgical procedure and select the training surgical procedure to be simulated; executing (408) the simulation; and evaluating (410) the operator’s performance of the simulated training surgical procedure by providing feedback via a user interface informing the user of differences between his or her actual performance of the training surgical procedure and a desired performance."

Claims 15 and 16 concern a computer program, which when executed on a computer performs the steps of any one of claims 10 to 14 and the computer program stored on a computer-readable medium, respectively.

IV. Reference is also made to the following document:

D2: US 2001/0020937 A.

V. The appellant in substance provided the following arguments:

The invention related to a surgical console, of the type described in document C1, for the control of instrumentation during real surgery adapted as a simulator, for training purposes. The examination division had started with C1, and simply stated that the surgical console it described could be used for instructing a trainee surgeon, when performing real live surgery. Obviously this would be no different to the uses and functioning of the surgical console of C1 in a real surgical setting. That was not relevant to the invention.
The examination division had failed to show any teaching in Cl to the skilled person as to the possibility of adapting the surgical console as a simulator machine, i.e. of having such a console double as an actual console for real surgery and as a console for simulated surgery, of how it could be so adapted, or setting it up or initializing it for performing a specific training exercise (not in a real surgical setting), or providing feedback for improving the trainees performance, all novel features which were claimed. The motivation to combine Cl and Dl, or for the skilled person to read them together, had not been shown. Without any hint or suggestion in Cl to use an actual surgical console in a simulation mode, or why or how it could be so adapted, it was not seen how the skilled reader would be led to take features from the dedicated surgical simulator of Dl, and then go on to apply them or adapt them to the actual surgical console of Cl. The skilled person could only regard this as a "normal option" with the benefit of hindsight of the invention claimed.

Moreover, there was no hint or suggestion in Dl that the processing module was adapted to provide feedback via the user interface informing the user of differences between his or her actual performance of the training surgical procedure and a desired performance. There was no provision in Dl for the storage of reference data comprising an ideal or desired performance against which the actual performance was compared, nor, as a result of that comparison, of any feedback provided by the processing module during the session informing the user of any measure of the differences between the actual and desired performance metrics.
Accordingly, the subject-matter of claim 1 involved an inventive step.

**Reasons for the Decision**

1. The appeal is admissible.

2. **Main request**

   2.1 **Amendments**

   Claim 1 as amended is based on claim 1 and the description as originally filed.

   In particular, the feature that the surgical console is operably useable in both actual surgical procedures and simulated surgical procedures is derivable from the fact that a commercially available console may be used, as indicated in the original description (cf page 7, lines 1 to 10).

   The feature that the processing module is adapted to perform the simulation is derivable from the original description (cf page 4, lines 18 to 19).

   The feature that the processing module is adapted to evaluate the operator's performance is inferable from the fact that according to the original description the processing module is operable to execute at least some of the steps discussed in the logic flow diagrams in the application (cf page 9, lines 19 to 21; page 17, lines 5 to 15 and figure 4).
The feature of providing feedback via the user interface is derivable from the original description (cf page 11, lines 2 to 7 and page 15, line 15 to page 16, line 3).

Claims 2 to 9 are based on the corresponding originally filed claims.

Claim 10 is based on claim 10 as originally filed, with amendments to correspond to claim 1.

Claims 11 to 16 are based on the corresponding originally filed claims.

Accordingly, the amendments comply with Article 123(2) EPC.

2.2 Novelty

2.2.1 Document C1

Document C1, cited in the application as originally filed, discloses a surgical console for operating microsurgical instruments notably for ophthalmic surgery (cf application, page 2, lines 1 to 8; document C1, column 1, lines 15 to 18).

In particular, document C1 discloses, using the terminology of claim 1, a surgical console operably useable in actual surgical procedures, comprising: a processing module (310) operable to direct operations of and receive inputs from peripheral devices (350) operably coupled to the surgical console, wherein the peripheral devices comprise surgical instruments; at least one memory device (328, 330) operably coupled to the processing module; and
a user interface (16, 18, 20) (cf column 3, line 35 to column 7, line 55; figures 1 to 3).

Moreover, as in substance held in the decision under appeal, the surgical console of C1 is also operably useable in simulated surgical procedures. In fact, this feature is not considered to define any structural limitation of the console. Clearly, the console of C1 is operably useable in simulated surgical procedures where for instance various operations on the console are practiced in the absence of a patient or where a surgical procedure is applied to a dummy object.

Accordingly, a console according to the pre-characterising portion of claim 1 is known from document C1.

Not disclosed in C1, however, are the features defined in the characterising portion of claim 1.

In particular, not disclosed in C1 is
- that the at least one memory device is operable to store a simulated training surgical procedure and multimedia content,
- that the user interface is adapted to permit the user to initialize the surgical console for a training surgical procedure and select the training surgical procedure to be simulated, and
- that the processing module is adapted to perform the simulation and evaluation the operator’s performance of the simulated training surgical procedure by providing feedback via the user interface informing the user of differences between his or her actual performance of the training surgical procedure and a desired performance.
Accordingly, the subject-matter of claim 1 is new over document C1 (Article 54(1) EPC 1973).

2.2.2 Document D1

Document D1 discloses a simulation device for eye operations.

The device includes a part simulating the operation instruments with one or two instruments, provided with sensors for the movements of the tool or tools, a computer unit with accompanying software translating the movements into a virtual image that in turn is shown on a display device (cf paragraph [0003], figures 1 and 4). In particular, the image generated in the computer is constructed partly by an eye and instrument image from the memory and also by the simulated instrument movements provided by the position sensors (cf paragraph [0021]). Furthermore, in order to improve the impression of reality, sounds are emitted through a loudspeaker corresponding to those heard when the instrument vibrates (cf paragraph [0019]).

Moreover, in D1, simultaneously with someone practicing on the simulation device, the picture that he or she sees can be shown on larger displays for tuition or evaluation, that is someone who can carry out an operation, checks how the practicing person carries out the simulated operation. It is of course also possible to record the session digitally, for instance for a repeating only of the parts of the operation that failed. The device thus not only enables training, but also evaluation of the achieved skill (cf paragraphs [0010] and [0026]). Moreover, by storing in the computer a three dimensional image of the eye and its different parts it is possible very precisely to keep
track of where the tips of the instruments are in relation to this and the computer can thus immediately "detect" if the membrane laying behind and holding the lens is injured. Such injuries and other mistakes at the operating must of course not occur at a real operation and one can thus not be content only with simulating of operations but one can furthermore check the quality of the simulated operation. This means that the practicing person can also get a measure of how good he or she has become and if progress is made or not (cf paragraph [0024]).

Accordingly, document D1 discloses, using the terminology of claim 1, a surgical console operably useable in simulated surgical procedures, comprising: a processing module (computer unit 3) operable to direct operations of and receive inputs from peripheral devices (operating instruments 1) operably coupled to the surgical console, wherein the peripheral devices comprise surgical instruments; at least one memory device operably coupled to the processing module; and a user interface (implicit for starting session, recording etc.).

Moreover, in D1 - the at least one memory device is operable to store a simulated training surgical procedure and multimedia content (image, sound, see above), - that the user interface is adapted to permit the user to initialize the surgical console for a training surgical procedure and select the training surgical procedure to be simulated (follows from the fact that eg only parts of the operation can be repeated, see above), and
- that the processing module is adapted to perform the simulation.

However, clearly the device of D1 is not useable in actual, real surgical procedures.

Moreover, in D1 the processing module (computer unit 3) is not adapted to evaluate the operator’s performance of the simulated training surgical procedure by providing feedback via the user interface informing the user of differences between his or her actual performance of the training surgical procedure and a desired performance.

As discussed above, in D1 a recording of the session as well as a simultaneous showing on larger displays is foreseen for evaluation. The assessment of any differences between the trainee's actual performance of the training surgical procedure and a desired performance is not performed by the device but by someone who can carry out the operation.

Moreover, as discussed above, in D1 the computer detects whether the membrane laying behind and holding the lens is injured. There is however no provision in D1 for storing reference information pertaining to the desired surgical procedure. This information is considered to involve more than just avoiding injuries to this membrane. Moreover, the computer in D1 does not establish a difference to any such reference information, neither does it provide corresponding feedback via a use interface.

Accordingly, the subject-matter of claim 1 is also new over document D1 (Article 54(1) EPC 1973).
2.2.3 The subject-matter of claim 1 is also new over the remaining available, more remote prior art.

In particular, document D2 discloses a virtual reality system used to simulate a medical surgery procedure. A surgical tool is manipulated by a user and virtual reality images are displayed on a display screen of a digital processing system in response to such manipulations. The surgical tool is coupled to a mechanical apparatus with actuators generating forces and sensors interfacing with a computer (cf paragraphs [0057] to [0065], figure 1).

2.2.4 The above also applies, mutatis mutandis, to claim 10 directed at a corresponding computer-implemented method for operating a surgical console.

Accordingly, the subject-matter of claim 10 is also new, in particular over any one of documents C1, D1 and D2 (Article 54(1) EPC 1973).

2.3 Inventive step

2.3.1 Document C1, as discussed above, discloses a surgical console according to the pre-characterising portion of claim 1 and may accordingly be considered the closest prior art. In fact, document C1 is the prior art from which the application as originally filed starts.

The distinguishing features of claim 1 over C1, provided in the characterising portion of claim 1, allow the console to be used in a simulated surgical procedure and to provide feedback on the user performance.
The objective problem to be solved relative to document C1 may accordingly be formulated as to provide a surgical console that can be used to generate realistic surgical situations to enable training of inexperienced surgeons and surgical room personnel, corresponding to what is indicated in the application as filed (cf page 3, lines 14 to 16).

According to the decision under appeal, all features of the characterising portion of claim 1 were known from D1 and the skilled person would regard it as a normal option to include these features in the console described in document C1 in order to solve the above problem posed and thereby arrive at the solution as defined in claim 1.

The appellant argued that, however, the motivation to combine C1 and D1, or for the skilled person to read them together, had not been shown. Without any hint or suggestion in C1 to use an actual surgical console in a simulation mode, or why or how it could be so adapted, it was not seen how the skilled reader would be led to take features from the dedicated surgical simulator of D1, and then go on to apply them or adapt them to the actual surgical console of C1.

The board agrees with the examining division that the skilled person would have referred to document D1 in an attempt to solve to problem posed. However, as argued by the appellant, document D1 discloses a dedicated surgical simulation device. Absent any suggestion in D1, C1 or elsewhere to use a surgical console useable for actual surgical procedures and adapt it to also be useable in simulated surgical procedures, there is nothing suggesting the skilled person to include the features disclosed in document D1 in the console
described in document C1. Rather, in the board's judgement the only solution suggested by D1 is to provide a dedicated surgical console useable for simulations only.

Moreover, unlike what is held in the decision under appeal, as discussed above, in the board's judgement document D1 does not disclose that the processing module (computer module) is adapted to evaluate the operator’s performance of the simulated training surgical procedure by providing feedback via the user interface informing the user of differences between his or her actual performance of the training surgical procedure and a desired performance. In D1, when evaluating the operation by simultaneously checking on larger displays or by analysing the recording, the person able to carry out the operation informs the user of the differences, and not the computer module. Moreover, the detection of injuries to the membrane holding the lens is not considered to equate to providing the feedback claimed.

This adds to the finding that the subject-matter of claim 1 is not rendered obvious by the disclosure document D1.

The solution as claimed is not suggested by document D2 either, which is also concerned with a dedicated surgical simulator.

Accordingly, having regard to the available state of the art, the subject-matter of claim 1 is not obvious to a person skilled in the art and, thus, involves an inventive step (Article 56 EPC 1973).
2.3.2 The above also applies, mutatis mutandis, to claim 10 directed at a corresponding computer-implemented method for operating a surgical console.

Accordingly, the subject-matter of claim 10 also is not obvious to a person skilled in the art and, thus, involves an inventive step (Article 56 EPC 1973).

Claims 2 to 9 and 11 to 14 are dependent on claims 1 and 10, respectively, providing further limitations. The subject-matter of these claims, therefore, also involves an inventive step.

Claims 15 and 16 concern a computer program, which when executed on a computer performs the steps of any one of claims 10 to 14 and the computer program stored on a computer-readable medium, respectively.

It is noted that the computer program claimed is technical as it serves to control a technical piece of equipment (surgical console). The fact that the computer program is stored on technical means (computer-readable medium) renders it all the more technical. Accordingly, the subject-matter of claims 15 and 16 is not excluded from patentability under Article 52(2)(c) and (3) EPC.

Moreover, the subject-matter of these claims is new and involves an inventive step for the same reasons given above with respect to claims 10 to 14.

2.4 The patent application documents also meet the remaining requirements of the EPC, so that a patent can be granted on the basis of these documents.
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 first instance with the order to grant a patent with the following documents:

   Description: Pages 1 and 2 filed with letter of 14 January 2009; Pages 3 to 19 as originally filed;

   Claims: Nos. 1 to 16 of the main request filed with letter of 21 October 2010;

   Drawings: Sheets 1/4 to 4/4 as originally filed.

The Registrar: The Chairman:

S. Sánchez Chiquero G. Eliasson

Decision electronically authenticated