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**Datasheet for the decision  
of 7 February 2017**

**Case Number:** T 2425/12 - 3.2.02

**Application Number:** 02712210.0

**Publication Number:** 1367941

**IPC:** A61B8/08

**Language of the proceedings:** EN

**Title of invention:**

MEDICAL IMAGING AND NAVIGATION SYSTEM

**Applicant:**

Mediguide Ltd.

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2), 54(1)

RPBA Art. 13(1)

**Keyword:**

Added subject-matter - main request and auxiliary request I  
(no)

Novelty - main request and auxiliary request I (no)

Admissibility of auxiliary request II filed during oral  
proceedings (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 2425/12 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 7 February 2017**

**Appellant:** Mediguide Ltd.  
(Applicant) Advanced Technology Center,  
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31053 Haifa (IL)

**Representative:** Kramer Barske Schmidtchen  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 4 June 2012  
refusing European patent application No.  
02712210.0 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** M. Stern  
P. L. P. Weber

## **Summary of Facts and Submissions**

I. The applicant lodged an appeal, by notice received on 1 August 2012, against the decision of the Examining Division dispatched on 4 June 2012 refusing European application No. 02 712 210.0. The fee for appeal was paid on that same day and the statement setting out the grounds of appeal was received on 28 September 2012.

II. In the appealed decision, the Examining Division held that the subject-matter of claim 1 lacked novelty over the following document:

D1: WO-A-97/29682.

III. The Board summoned the appellant to oral proceedings, setting out its provisional opinion in a communication dated 28 October 2016. In addition to an objection under Article 123(2) EPC, it presented the reasons for its provisional view that the subject-matter of claim 1 lacked novelty over document D1.

IV. Oral proceedings took place on 7 February 2017.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, of auxiliary request I, both filed with letter dated 4 January 2017, or auxiliary request II, filed during the oral proceedings.

V. Claim 1 of the different requests reads as follows (the differences to the main request are highlighted by the Board):

**Main request:**

"1. Medical imaging and navigation system (100, 400, 450) comprising:

    a processor (102, 286, 402, 460), coupled with a display unit (130, 284, 430, 466) and to a database (114, 274, 414);

    a medical positioning system (MPS) (108, 288, 408, 456), coupled with said processor (102, 286, 402, 460), including a transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>) and a surgical tool MPS sensor (162<sub>1</sub>, 432<sub>1</sub>), said surgical tool MPS sensor being firmly attached to a surgical tool (120, 420, 452),

    a two-dimensional imaging system (104, 404, 454), coupled with said processor (102, 286, 402, 460), including an imaging transducer (118, 418), said transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>) being firmly attached to said imaging transducer (118, 418);

    an inspected organ monitor interface coupled with said processor (102, 402, 460) and to an organ monitor (106, 278, 406, 464), said organ monitor (106, 278, 406, 464) is adapted to monitor an organ timing signal associated with an inspected organ; and

    a superimposing processor (116, 272, 416), coupled with said processor (102, 286, 402, 460),

    wherein said processor (102, 402, 460) is adapted to receive:

        a plurality of two-dimensional images from said two-dimensional imaging system (104, 404, 454), acquired by said imaging transducer (118, 418);

        the location and orientation of said imaging transducer (118, 418) from said medical positioning system (108, 288, 408, 456), as detected by said transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>), for each said two-dimensional images;

said organ timing signal from said inspected organ monitor interface, as detected by said organ monitor (106, 278, 406, 464), for each said two-dimensional images; and

the location and orientation of said surgical tool (120, 420, 452), from said medical positioning system (108, 288, 408, 456), as detected by said surgical tool MPS sensor (162<sub>1</sub>, 432<sub>1</sub>)

wherein said location and orientation of said surgical tool (120, 420, 452) and said location and orientation of said imaging transducer (118, 418), reside in a single coordinate system;

wherein for each said two-dimensional images, said processor (102, 286, 402, 460) is adapted to store said two-dimensional images in said database (114, 274, 414) together with said location and orientation information of said imaging transducer (118, 148), respective of said two-dimensional image and said organ timing signal, respective of said two-dimensional image,

wherein said processor (102, 286, 402, 460) is adapted to select at least one of said stored two-dimensional images, having a stored organ timing signal substantially equal to a real time detected organ timing signal detected by the organ monitor (106, 278, 406, 464),

wherein said superimposing processor (116, 272, 416) is adapted to superimpose a representation of said surgical tool (120, 420, 452) on a visual representation of said selected two-dimensional images, and

wherein said display (130, 284, 430, 466) is adapted to present the result of said superimposing."

**Auxiliary request I:**

"1. Medical imaging and navigation system (100, 400, 450) comprising:

a surgical tool (102, 286, 402, 460);

a processor (102, 286, 402, 460), coupled with a display unit (130, 284, 430, 466) and to a database (114, 274, 414);

a medical positioning system (MPS) (108, 288, 408, 456), coupled with said processor (102, 286, 402, 460), including a transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>) and a surgical tool MPS sensor (162<sub>1</sub>, 432<sub>1</sub>), said surgical tool MPS sensor being firmly attached to a the surgical tool (120, 420, 452),

a two-dimensional imaging system (104, 404, 454), coupled with said processor (102, 286, 402, 460), including an imaging transducer (118, 418), said transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>) being firmly attached to said imaging transducer (118, 418);

an inspected organ monitor interface coupled with said processor (102, 402, 460) and to an organ monitor (106, 278, 406, 464), said organ monitor (106, 278, 406, 464) is adapted to monitor an organ timing signal associated with an inspected organ; and

a superimposing processor (116, 272, 416), coupled with said processor (102, 286, 402, 460),

wherein said processor (102, 402, 460) is adapted to receive:

a plurality of two-dimensional images from said two-dimensional imaging system (104, 404, 454), acquired by said imaging transducer (118, 418);

the location and orientation of said imaging transducer (118, 418) from said medical positioning system (108, 288, 408, 456), as detected by said transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>), for each said two-dimensional images;

said organ timing signal from said inspected organ monitor interface, as detected by said organ monitor (106, 278, 406, 464), for each said two-dimensional images; and

the location and orientation of said surgical tool (120, 420, 452), from said medical positioning system (108, 288, 408, 456), as detected by said surgical tool MPS sensor (162<sub>1</sub>, 432<sub>1</sub>)

wherein said location and orientation of said surgical tool (120, 420, 452) and said location and orientation of said imaging transducer (118, 418), reside in a single coordinate system;

wherein for each said two-dimensional images, said processor (102, 286, 402, 460) is adapted to store said two-dimensional images in said database (114, 274, 414) together with said location and orientation information of said imaging transducer (118, 148), respective of said two-dimensional image and said organ timing signal, respective of said two-dimensional image,

wherein said processor (102, 286, 402, 460) is adapted to select at least one of said stored two-dimensional images, having a stored organ timing signal substantially equal to a real time detected organ timing signal detected by the organ monitor (106, 278, 406, 464),

wherein said superimposing processor (116, 272, 416) is adapted to superimpose a representation of said surgical tool (120, 420, 452) on a visual representation of said selected two-dimensional images, and

wherein said display (130, 284, 430, 466) is adapted to present the result of said superimposing."



**Auxiliary request II:**

"1. Medical imaging and navigation system (100, 400, 450) comprising:

a processor (102, 286, 402, 460), coupled with a display unit (130, 284, 430, 466) and to a database (114, 274, 414);

a medical positioning system (MPS) (108, 288, 408, 456), coupled with said processor (102, 286, 402, 460), including a transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>) and a surgical tool MPS sensor (162<sub>1</sub>, 432<sub>1</sub>), said surgical tool MPS sensor being firmly attached to a surgical tool (120, 420, 452),

a two-dimensional imaging system (104, 404, 454), coupled with said processor (102, 286, 402, 460), including an imaging transducer (118, 418), said transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>) being firmly attached to said imaging transducer (118, 418);

an inspected organ monitor interface coupled with said processor (102, 402, 460) and to an organ monitor (106, 278, 406, 464), said organ monitor (106, 278, 406, 464) is adapted to monitor an organ timing signal associated with an inspected organ having a cyclic behaviour such that an organ timing signal reading in one cycle is likely to be detected in subsequent cycles; and

a superimposing processor (116, 272, 416), coupled with said processor (102, 286, 402, 460),

wherein said processor (102, 402, 460) is adapted to receive:

a plurality of two-dimensional images from said two-dimensional imaging system (104, 404, 454), acquired by said imaging transducer (118, 418);

the location and orientation of said imaging transducer (118, 418) from said medical positioning system (108, 288, 408, 456), as detected by said

transducer MPS sensor (162<sub>2</sub>, 432<sub>2</sub>), for each said two-dimensional images;

~~said~~ an organ timing signal reading from said inspected organ monitor interface, as detected by said organ monitor (106, 278, 406, 464), for each said two-dimensional images; and

the location and orientation of said surgical tool (120, 420, 452), from said medical positioning system (108, 288, 408, 456), as detected by said surgical tool MPS sensor (162<sub>1</sub>, 432<sub>1</sub>)

wherein said location and orientation of said surgical tool (120, 420, 452) and said location and orientation of said imaging transducer (118, 418), reside in a single coordinate system;

wherein for each said two-dimensional images, said processor (102, 286, 402, 460) is adapted to store said two-dimensional images in said database (114, 274, 414) together with said location and orientation information of said imaging transducer (118, 148), respective of said two-dimensional image and said organ timing signal, ~~respective of said two-dimensional image~~ reading,

wherein said processor (102, 286, 402, 460) is adapted to select at least one of said stored two-dimensional images, having a stored organ timing signal reading substantially equal to a real time detected organ timing signal reading detected by the organ monitor (106, 278, 406, 464), and to reconstruct a three-dimensional image from all of the stored two-dimensional images which have the same timing signal reading for displaying a sequence of three-dimensional images synchronized with a real-time reading of the organ timing signal,

wherein said superimposing processor (116, 272, 416) is adapted to superimpose a representation of said surgical tool (120, 420, 452) ~~on a visual~~

representation of said selected two-dimensional images on a currently displayed three-dimensional image, and wherein said display (130, 284, 430, 466) is adapted to present the result of said superimposing."

VI. The arguments of the appellant are summarised as follows:

Claim 1 of the main request and auxiliary request I was novel over D1. In particular, the passage on page 23, lines 8 to 23 of D1 did not anticipate the following features: (a) for each of the two-dimensional images, the processor is adapted to store the two-dimensional image in the database together with the organ timing signal, and (b) the processor is adapted to select at least one of the stored two-dimensional images, having a stored organ timing signal substantially equal to a real time detected organ timing signal detected by the organ monitor. Claim 1 required a relationship between each image and the organ timing signal, and D1 had to do more than simply disclose that both images and organ timing were captured without any logical relationship between the two. D1 failed to suggest or imply a processor storing a two-dimensional image together with an organ timing signal respective of the image. Furthermore, D1 did not disclose a processor selecting a stored two-dimensional image having a stored organ timing signal substantially equal to a real time detected organ timing signal. It was not directly disclosed either that the subject-matter of claims 43 to 46 referred to the embodiment described on page 23. This embodiment, moreover, was merely disclosed in broad terms, without any specific reference to a two-dimensional image or a surgical tool. Lastly, D1 did not teach that the stored location and orientation information of the surgical tool, and the location and

orientation of the imaging transducer, resided in a single coordinate system, so that in D1 these locations and orientations were not detected using the same medical positioning system.

Auxiliary request II should be admitted into the appeal proceedings since it had been filed in response to the Board not being persuaded by the arguments presented during oral proceedings in defence of the main request and auxiliary request I.

### **Reasons for the Decision**

1. The appeal is admissible.
2. In response to the Board's communication attached to the summons to oral proceedings, claim 1 of the main request and auxiliary request I was filed. It included the definitions of the surgical tool positioning sensor "being is adapted to be firmly attached" to the surgical tool and of the transducer positioning sensor "being is adapted to be firmly attached" to the imaging transducer. These amendments overcome the objection under Article 123(2) EPC which the Board raised in its communication.

The Board therefore considers that claim 1 of the main request and of auxiliary request I is properly based on claims 1 to 4 and page 39, lines 16 to 20 of the application as filed, thereby satisfying the requirements of Article 123(2) EPC.

3. *The invention*

The imaging and navigation system of the invention allows to image the motion of a surgical tool inside a patient in spite of movements in his body caused e.g. by heart beat or breathing. These movements are detected by an "organ monitor" (such as an ECG) monitoring an organ timing signal. The surgical tool is imaged with a two-dimensional imaging transducer (e.g. an ultrasound transducer), the location and orientation of the surgical tool and of the imaging transducer being determined using a medical positioning system (MPS). The claimed system stores the two-dimensional images together with the location and orientation of the surgical tool from the MPS and the organ timing signal, and selects one (or more) of the images having a stored organ timing signal substantially equal to a detected real-time organ timing signal. The system display superimposes a representation of the surgical tool on a visual representation of the selected two-dimensional image(s).

4. *Novelty*

4.1 Document D1 describes on page 23, lines 21 to 28 and depicts in Figure 11 a block diagram of a system for imaging and guiding a probe. The system comprises a probe (308) and an imager (312), each having a position sensor (310 and 314), and a processor (302) which displays on a display (304) an indication of the position of the probe superimposed on an image retrieved from an image store (316). In the context of a previously described embodiment (page 14, lines 19 to 21; Figure 2), D1 specifies the probe as a biopsy needle (50) with an attached position sensor (64) and the imager as a two-dimensional ultrasound imager (54)

with an attached position sensor (60). The skilled person would certainly understand that these specific features presented in Figure 2 are examples of the more general features appearing in the block diagram of the system depicted in Figure 11.

Hence, the probe mentioned on page 23 of D1 is, in the terminology of claim 1, a "surgical tool". As the system depicted in Figure 11 is disclosed to be suited for applying the previously described guidance methods (page 23, lines 21 to 23), the system is an imaging and navigation system for a surgical tool as defined in claim 1.

4.2 According to one of the guidance methods disclosed on page 23, lines 16 and 17, a composite reference image is generated at each instant by interpolating between existing images (which, as mentioned at lines 8 and 9, are obtained by the ultrasound imager). It is clear to the skilled person that such an interpolation of images at each instant can only be carried out once the images used for the interpolation calculation have been stored in the processor. As indicated under point 4.1 above, the images of the ultrasound imager are two-dimensional.

Moreover, claims 43 to 46 of D1 specify further details about the generation, selection and storage of the reference images. Claim 43 specifies a method of selecting a reference image such that it has a motion phase substantially corresponding to the motion phase of the rhythmic motion of the patient's body (lines 15 to 16 of claim 43). The motion is detected by a physiological motion monitor (claim 46) such as an ECG (page 23, lines 11 to 14). According to claim 45, the reference image is generated by

interpolation from a plurality of images (page 23, lines 16 and 17). It is clear to the skilled person that if the reference image is to be selected such that it has a motion phase substantially corresponding to the detected motion phase, each of the images used in calculating the reference image needs to carry some information about the motion phase too. Thus, contrary to the appellant's view, it is implicit in the disclosure of D1 that each of the stored images is stored together with pertinent information about the motion phase detected by the physiological motion monitor, i.e. with an "organ timing signal".

Thus, in the words of claim 1 of the main request, in D1 each two-dimensional image needs to be stored together with its respective "organ timing signal" and the processor selects one image having a stored organ timing signal which is "substantially equal" to a real-time detected organ timing signal detected by the "organ monitor".

- 4.3 The appellant also argued that it was not directly disclosed that the subject-matter of claims 43 to 46 referred to the embodiment described on page 23.

The Board does not accept this argument. Page 23, lines 16 and 17 refers to the generation of reference images at each instant by interpolation between obtained images, and precisely such a generation of reference images is further specified in claims 43 to 46. Even if these further details defined in the claims were omitted from the description, the skilled person would immediately recognise the technical interrelationship between the features of page 23 of the description and the corresponding ones in claims 43 to 46.

The appellant's further contention that the embodiment on page 23 is broadly disclosed without making specific reference to a two-dimensional image or to a surgical tool is also not convincing. As explained under point 4.1 above, the skilled person would clearly understand that the features of the embodiment of Figure 2 are specific examples of the broader corresponding features disclosed in relation to the system of page 23, lines 7 to 28.

- 4.4 The Board was not convinced either by the appellant's argument that D1 did not teach that the stored location and orientation information of the surgical tool, and the location and orientation of the imaging transducer, resided in a single coordinate system. The position sensors attached to the surgical tool and the image transducer are explicitly disclosed as RF-signal emitters (page 17, lines 36 to 38). This, however, implies that the system must comprise an RF detection system too in order to detect the emitted position signals. Such detection system may be said to define a "single coordinate system" in which the location and orientation of the surgical tool and transducer with their emitters "reside", as defined in claim 1.
- 4.5 In view of the above, the Board concludes that the subject-matter of claim 1 of the main request lacks novelty within the meaning of Article 54(1) EPC.
- 4.6 Since claim 1 of auxiliary request I is, uncontestedly, in substance identical to claim 1 of the main request, the same conclusion applies to auxiliary request I too.



5. *Admissibility of auxiliary request II*

5.1 The appellant filed auxiliary request II only at the end of the oral proceedings, after the Board had announced its conclusion that the subject-matter of the main request and auxiliary request I did not fulfil the requirement of novelty over D1.

5.2 It is the established jurisprudence of the boards of appeal that the appeal procedure is designed to ensure that the proceedings are as brief and concentrated as possible and ready for decision at the conclusion of oral proceedings. Therefore, amendments to the claims must be filed at the earliest possible moment and the Board has discretion under Article 13(1) RPBA to disregard amended claims if they are not filed at the earliest possible moment, and in particular if they are not filed in good time prior to oral proceedings (Case Law of the Boards of Appeal, 8th edition 2016, IV.E. 4.2). The Board must exercise that discretion in view inter alia of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

5.3 In the present case, the Board sees no justifiable reason for the appellant to have waited until the end of the oral proceedings before filing auxiliary request II.

The only justification given by the appellant was that it was responding to the Board not having been persuaded by its arguments during the oral proceedings in defence of its previous requests.

The Board disagrees with the appellant's view that an unfavourable outcome of its case during oral proceedings can in itself justify filing an amended set of claims at the end of those proceedings. The oral proceedings did not present any new, let alone unforeseeable, developments concerning the novelty objection raised in the Board's communication attached to the summons to oral proceedings. That the appellant's arguments during the oral proceedings did not convince the Board is not an unforeseeable development.

Moreover, the Board's communication included an explicit caveat regarding late filings, citing the provisions of Article 114(2) EPC and Articles 12 and 13 RPBA. Whilst the appellant filed about one month before the oral proceedings the main request and auxiliary request I in order to overcome the objection under Article 123(2) EPC raised in the Board's communication, nothing prevented it from filing auxiliary request II too, at the same time, as an additional fall-back position regarding the novelty objection raised in the communication. Claim 1 of auxiliary request II included additional features, extracted in part from a lengthy description of about 80 pages, which define the reconstruction of a three-dimensional image from the stored two-dimensional images. In view of the complexity of the subject-matter as thus amended, the Board considers that it is inappropriate to examine the patentability of the newly filed request for the first time during the oral proceedings.

5.4 Hence, the Board finds auxiliary request II to be inadmissible under Article 13(1) RPBA.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated