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Datasheet for the decision of 26 February 2015

Case Number: T 1151/11 - 3.2.02

Application Number: 03753604.2

Publication Number: 1554987

IPC: A61B19/00, A61B6/00

Language of the proceedings: EN

Title of invention:
FUNCTIONAL NAVIGATOR

Patent Proprietor:
CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS
UNIVERSIDAD POLITECNICA DE VALENCIA

Opponent:
SurgicEye GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c), 83, 123(2), 123(3), 54, 56
RPBA Art. 12(2), 12(4), 15(3)
EPC R. 115(2)

Keyword:
Substantiation of some objections in the reply to the statement of grounds (no)
Oral proceedings - held in absence of respondent
Sufficiency of disclosure - (yes)
Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0002/10

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 1151/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 26 February 2015

Appellant: (Patent Proprietor 1)	CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS Serrano, 117 28006 Madrid (ES)
Appellant: (Patent Proprietor 2)	UNIVERSIDAD POLITECNICA DE VALENCIA Camino de Vera s/n 46022 Valencia (ES)
Representative:	Grünecker, Kinkeldey, Stockmair & Schwanhäusser Anwaltssozietät Leopoldstrasse 4 80802 München (DE)
Respondent: (Opponent)	SurgicEye GmbH Friedenstrasse 18a 81671 München (DE)
Representative:	Zimmermann & Partner Postfach 330 920 80069 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 March 2011 revoking European patent No. 1554987 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	P. L. P. Weber

Summary of Facts and Submissions

I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 7 March 2011, to revoke European patent No. 1 554 987.

II. The opposition was filed on the grounds that:

a) the subject-matter of the patent was not patentable as it related to methods of treatment according to Article 53(c) EPC, was not novel and was not inventive (Article 100(a) EPC);

b) the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC); and

c) the subject-matter of the patent extended beyond the content of the application as filed (Article 100(c) EPC).

III. In its decision the Opposition Division found that the grounds for opposition according to Article 100(b) and (c) EPC did not prejudice the maintenance of the patent and that the subject-matter of the patent did not relate to methods of treatment according to Article 53(c) EPC.

In relation to novelty and inventive step, the Opposition Division analysed the following documents:

D1: WO-A-01/79884;
D3: WO-A-02/060316.

It held that while auxiliary request 2 as then on file

did not fulfil the clarity requirements of Article 84 EPC, the other requests in the proceedings did not fulfil the requirements of novelty and inventive step in view of these two documents.

IV. The notice of appeal was received on 17 May 2011. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 18 July 2011, which was a Monday.

V. The respondent's reply to the statement of grounds was received on 7 February 2012.

VI. The Board summoned the parties to oral proceedings and set out its provisional opinion by a communication dated 21 November 2014.

VII. The respondent announced by letter dated 24 February 2015 that it would not attend the oral proceedings. These were held on 26 February 2015 in the respondent's absence.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed during the oral proceedings.

IX. The respondent had requested in writing that the appeal be dismissed.

X. The following documents are also mentioned in the present decision:

D2: US-A-2001/0029333;
D6: DE-A-100 37 491.

XI. Claim 1 of the main request, which corresponds to claim 1 of auxiliary request 2 as filed with the statement of grounds, reads as follows:

"A system for coordinating a surgery process comprising:
a standard surgical navigator comprising structural 3D imaging capabilities and providing a morphological CAT or magnetic resonance image obtained before the surgery process;
a gamma camera or a plurality of gamma cameras for obtaining functional 3D images showing the metabolic activity of cells of organs or tissues in real time,
surgical instruments,
position finding elements located on said surgical instruments and said gamma camera or cameras to correlate said gamma camera or cameras and said surgical instruments with said navigator;
a specific software program which combines all information from the aforementioned elements;
wherein the functional images are processed and combined with the morphological image and used to identify different metabolic activity threshold areas of affected tissues to be monitored in order to permit the surgical instruments to be positioned with regard to said areas."

XII. Claims 2 to 4 are dependent claims.

XIII. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

a) Basis in the original application

The subject-matter of claim 1 was based on the general teaching of the description of the

application as filed.

In particular, the claimed feature of the functional images combined with the morphological image used to identify different metabolic activity threshold areas of affected tissues to be monitored was not explicitly disclosed, but was inherent in the displaying of the combined image. This image represented areas of tissue in a different manner, e.g. in a grayscale or colour scale, depending on their metabolic activity. Based on the displayed image, it was left to the surgeon to identify the different metabolic activity threshold areas of affected tissue to be monitored, as required by claim 1. The claimed feature required no more than the specific software program superimposing the two images.

b) Novelty

Document D1 described a tomographic imaging system with a handheld camera providing a 3D representation of a gamma ray source, i.e. a functional image. It failed to disclose that the system comprised a surgical navigator with structural 3D imaging capabilities. The fact that morphological information was also provided by the functional image could not amount to a disclosure of a morphological image within the meaning of claim 1, since the claim made a clear distinction between functional and morphological images, which had to be combined. Paragraph [0064] of document D1, referred to in the impugned decision, taught "to register data from anatomic imaging modalities such as ultrasound or magnetic resonance imaging to demonstrate needle tips or other landmarks of

interest". Paragraph [0067] described the correlation of a needle with the functional image. However, no combination of a morphological image with a structural image within the meaning of claim 1 was envisaged.

It followed that the subject-matter of claim 1 was novel over document D1.

Document D3 disclosed a radiolocalisation system providing three-dimensional localisation information of a sentinel node by means of two gamma detectors. That information was used to determine the spatial location and coordinates of the sentinel node. The location or image of the sentinel node was then overlaid on a real time image of a separate imaging system. No combination of 3D functional images in real time with morphological images was envisaged in D3. Moreover, D3 did not teach a surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process, since it taught that the separate imaging system employed a real-time ultrasound technology, which provided images during the surgery process.

It followed that the subject-matter of claim 1 was novel over document D3, too.

c) Inventive step

Document D3 was the closest prior art.

The feature of the surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process addressed the

problem of providing a system for coordinating a surgery process with an accurate control of the surgical instruments.

Document D1 disclosed that magnetic resonance imaging could be used to provide anatomic data for use by a surgical navigator (paragraph [0064]). However, document D3 stressed that, in its system, the morphological data should be provided real-time for better identification of an appropriate penetration path for targeting the sentinel node (paragraph bridging pages 9 and 10). In general, this taught away from obtaining an image before the surgery process as claimed in claim 1. More particularly, it also taught away from the magnetic resonance imaging as disclosed in document D1, which, as such, would not be easy to implement in the operation room, during surgery.

It followed that the subject-matter of claim 1 involved an inventive step.

XIV. The respondent referred to all the arguments provided in support of the respective objections formulated in the proceedings before the first instance and affirmed that they continued to be relevant. Its arguments specifically presented in the appeal proceedings, as far as relevant for the present decision, may be summarised as follows:

a) Sufficiency of disclosure

The invention as claimed in claim 1 required that a specific software program combined functional images and a morphological CAT or magnetic resonance image obtained before the surgery

process. However the patent did not provide any teaching as to how such a complex combination should look. Should the Board consider that the person skilled in the art would generally know how to combine the functional images with the morphological image, then the combination could not contribute to inventive step.

b) Basis in the original application

Generally, the common knowledge of a person skilled in the art could not be considered as originally disclosed in the application as long as it had not been presented in it.

For example, the concept of threshold areas as claimed in claim 1 had definitely not been implicitly disclosed, as it was not directly and unambiguously derivable from the originally filed documents. It was irrelevant whether the skilled person might know that image processing techniques involving gamma cameras worked on the basis of threshold values or threshold areas.

The feature claimed in claim 1 that the standard surgical navigator provided a morphological CAT or magnetic resonance image obtained before the surgery process had not been originally disclosed either. The passage in paragraph [0008] of the patent mentioning such imaging methods read:

> *"Navigators are extraordinarily useful devices in intra-operative work since they permit surgical instruments (scalpels, clamps, etc.) to be located with a high degree of precision with regard to the patient's organs or tumors*

by comparing them with a CAT or Magnetic Resonance image taken prior to the operation."

That passage described known navigators but it did not disclose that they could be part of the claimed invention. Moreover, the passage only mentioned that the navigator compared the images and not that it provided them. Most importantly, however, if it required an inventive step to combine real-time images with morphological images obtained prior to the operation and exactly that was the contribution of the claimed invention over the prior art, the question would arise why the whole patent did not devote a single word to this combination. It could rather be concluded that the feature of the standard surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process did not belong to the invention at the time of filing of the original application.

It followed that the requirements of Article 123(2) EPC were not fulfilled.

c) Novelty

Document D1 was novelty-destroying for the subject-matter of claim 1. In particular, paragraph [0064] taught that it was possible to register images to demonstrate needle tips or other landmarks of interest. Those were morphological images within the meaning of the patent. Moreover, in the same paragraph, it was disclosed that morphological information was relayed to the computer that displayed the functional images. It followed that the

morphological information was also displayed. As a result, the combination of the functional images with the morphological image as claimed in claim 1 was disclosed in that paragraph [0064].

Document D3 was also novelty-destroying for the subject-matter of claim 1. In particular, the disclosure on page 14, from line 24 on, was to overlay functional images with a real-time ultrasound image, i.e. a morphological image. The functional images inherently showed the metabolic activity of cells of organs or tissues, as defined in claim 1. As the appellant, too, had submitted when arguing about the basis in the original application for the feature that the standard surgical navigator provided a morphological CAT or magnetic resonance image obtained before the surgery process, known navigators provided a morphological image obtained before the surgery process. The skilled person would therefore read the disclosure of document D3 as implying that feature, too.

d) Inventive step

In the event that the subject-matter of claim 1 was considered novel, it could not be seen as inventive in view of document D2, abstract and document D6, paragraph [0016], which taught the provision of CAT or magnetic resonance images obtained before a surgery process.

Reasons for the Decision

1. The appeal is admissible.

2. The respondent, who had been duly summoned, informed the Board that it did not intend to attend the oral proceedings. The Board decided to continue the proceedings without that party under Rule 115(2) EPC and Article 15(3) RPBA. Accordingly, the respondent is treated as relying only on its written case.

3. In its reply to the statement of grounds the respondent generally referred to all the arguments submitted in the proceedings before the first instance in addition to its arguments as summarised above.

   Such a general reference to submissions in the proceedings before the department of first instance cannot be considered as specifying expressly the arguments relied on by the respondent, since it would thereby be left to the Board and to the other party to find out which parts of such submissions are relevant to which parts of the impugned decision or of the arguments of the other party.

   Therefore, under Article 12(2) and (4) RPBA, the Board will only take into account the respondent's arguments which were specifically presented in the appeal proceedings and are summarised as such above.

4. The appellant's main request was filed during the oral proceedings, in the respondent's absence. However, all the claims of this request were already present in auxiliary request 2 filed with the statement of grounds of appeal. Hence, the Board admits the appellant's main

request into the proceedings.

5. *The invention*

The invention concerns a system for coordinating a surgery process, comprising a surgical navigator, surgical instruments and one or more gamma cameras for obtaining functional 3D images in real time of the area to be operated.

As described in the patent, surgical navigators are used especially in the field of neurosurgery and permit surgical instruments to be positioned within the human body with a high degree of precision. They typically make use of CAT or magnetic resonance morphological images taken prior to the operation in order to locate and guide the surgical instruments to the area to be operated on (paragraph [0008]).

Gamma cameras detect the metabolic activity of organs or tissues and provide functional images of an area of interest within the body. These functional images may be used to detect abnormal functioning of an organ or region, which may be a sign of a metabolic disorder, such as cancer.

According to the invention, the functional images provided by a gamma camera or a plurality of gamma cameras in real time together with the morphological image provided by the navigator are processed and combined in order to permit the surgical instruments to be positioned with regard to the area to be operated on. That allows the surgeon to decide better upon the extent of the operation required. In particular, in the case of cancer, the information conveyed by the combined image may be used in order to decide whether

ganglia in the vicinity of the tumor could be carcinogenic and, hence, whether it should be removed or not.

6. *Sufficiency of disclosure*

As the respondent submitted, the invention as defined in claim 1 requires that a specific software program combines functional images and a morphological CAT or magnetic resonance image obtained before the surgery process.

While it can be agreed that no specific information about the software is given in the patent, the Board shares the Opposition Division's view expressed in the impugned decision (point 13.2 of the Reasons) that such image combinations are per se known to the person skilled in image processing techniques. The invention does not stress the importance of any specific image combination technique. Hence, how the two images should actually be combined and displayed is a secondary matter for the software programmer to choose and implement, without the need for any further detailed explanation.

As regards the other claimed features, the Board is also of the opinion that the skilled person can implement them based on common general knowledge and the teaching of the patent.

It follows that the invention as claimed in the main request is disclosed in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art. Hence, Articles 83 and 100(b) EPC do not prejudice the maintenance of the patent according to

the main request.

7. *Basis in the original application and extension of the scope of protection*

7.1 The respondent argued that the features of claim 1 relating to the identification of threshold areas and the standard surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process had not been disclosed in the application as originally filed, thereby contravening Article 123(2) EPC.

In accordance with decision G 2/10, the Board notes that the "gold standard" for assessing compliance with Article 123(2) EPC is to establish whether the skilled person is "presented with technical information which he would not derive directly and unambiguously, using common general knowledge, from the application as filed". It follows that it has also to be duly taken into account what the skilled person generally would know about a certain feature, even if only mentioned but not described in detail in the original application.

As regards the claimed feature of the functional images combined with the morphological image used to identify different metabolic activity threshold areas of affected tissues to be monitored, the Board agrees with the appellant's view and the finding in the impugned decision that the combined image would inherently represent areas of tissue in a different manner, e.g. in a grayscale or colour scale, depending on their metabolic activity. Hence, different metabolic activity areas are implicitly distinguished.

Based on the teaching of the patent as a whole, the Board does not share the Opposition Division's interpretation of the claim, as expressed in point 13.3 of the Reasons of the impugned decision, according to which it is the software program that automatically performs the identification of different metabolic activity threshold areas of affected tissue to be monitored. For example, paragraph [0020] of the patent, which corresponds to paragraph [0021] of the original application as published, explains that the software program forms "a complete morphological and functional image, which is of extraordinary utility for the surgeon".

As also submitted by the appellant, the claim must therefore be interpreted rather as simply requiring, in this respect, that the surgeon is presented with a combined image enabling him to perform readily the identification. That is an implicit consequence of the specific software program superimposing the two images and distinguishing different metabolic activity areas.

As a result, the Board is satisfied that the claimed feature of the functional images combined with the morphological image used to identify different metabolic activity threshold areas of affected tissues to be monitored has a basis in the application as originally filed.

Concerning the standard surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process, the Board notes that in paragraphs [0012] and [0013] of the original application as published it is disclosed that the idea behind the invention is to associate a surgical navigator with three-dimensional functional images.

Hence, the skilled person would readily understand that the core of the invention does not lie in the surgical navigator as such, which could be of a standard type.

From the description in the original application of the navigators of the prior art, in particular paragraph [0008] of the published version, the skilled person would directly and unambiguously derive what a standard surgical navigator within the meaning of the invention is.

Furthermore, as the respondent also pointed out, this paragraph teaches that navigators of the prior art "permit surgical instruments (scalpels, clamps, etc.) to be located with a high degree of precision with regard to the patient's organs or tumours by comparing them with a CAT or Magnetic Resonance image taken prior to the operation". Hence, the person skilled in the art would directly and unambiguously recognise that those navigators provide such images too.

The respondent's argument that the described navigators merely compare the images but do not provide them cannot be accepted. In order to be able to compare images, those images have to be present. If the comparison is made by the navigator, it necessarily follows that the navigator is provided with the images and therefore also provides them within the meaning of claim 1.

The respondent's argument based on the alleged importance of the combination of real-time functional images with a morphological CAT or magnetic resonance image obtained before the surgery process and the lack of any specific disclosure of such a combination in the original application is not convincing either. As

already mentioned, the claimed invention does not stress the importance of any specific image combination technique, but rather of the provision of any combined image with functional and morphological information, the latter deriving from a CAT or magnetic resonance image obtained before the surgery process.

As a result, the Board is also satisfied that the claimed feature of the standard surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process has a basis in the application as originally filed.

As regards the other claimed features, they find a basis in particular in paragraphs [0008], [0013], [0015], [0021], [0029] and [0032].

Hence, the Board concludes that the requirements of Article 123(2) EPC are fulfilled.

7.2 Compared with claim 1 of the patent as granted the scope of claim 1 of the main request has been limited by the addition of further features of the standard surgical navigator and the gamma camera or the plurality of gamma cameras. The dependent claims were already present in the granted version.

Hence the Board is satisfied that the requirements of Article 123(3) EPC are also fulfilled.

8. Novelty

The respondent submitted that documents D1 and D3 were novelty-destroying for the subject-matter of claim 1 of the main request. In the impugned decision, when considering the patentability of the then pending first

auxiliary request (points 18 and 19 of the Reasons), the Opposition Division found that the feature of the standard surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process conferred novelty, but did not contribute to an inventive step in view of document D1.

8.1 In the Board's view, document D1 essentially concerns the use of one or more gamma cameras for obtaining a three-dimensional representation of "target lesions and overlying tissues" which emit radiation (paragraphs [0002] and [0013], in particular).

In point 16.3 of the impugned decision the Opposition Division held that no specific features of a structural or morphological image were defined in claim 1 of the main request as then pending and that the functional images of document D1 comprised morphological information. This reasoning would apply to claim 1 of the main request in the present appeal proceedings, too.

However, in the Board's view, the different denomination of *structural* (or *morphological*) and *functional* images in claim 1 requires that the images in question be distinct. Hence, the images provided by the gamma cameras of document D1 cannot be considered to be at the same time functional and structural within the meaning of claim 1.

As the respondent also observed, paragraph [0064] mentions "to register data from anatomic imaging modalities" to "demonstrate needle tips or other landmarks of interest". Furthermore, according to the same paragraph, the registered data is relayed to a computer that displays the functional 3D images.

However, document D1 is silent on how this demonstration should be done. In particular, there is no teaching that it should be performed by providing a morphological image which is then combined with the processed functional images by a specific software program, as required by claim 1. In view of the fact that, according to paragraph [0064] of document D1, the registration of the data relayed to the computer "can be accomplished using position sensors that are touched by the user to fiduciary markers visible in the anatomic imaging modality or to the naked eye", the skilled person would rather understand that, most likely, only the coordinates - not the images - of the "needle tips or other landmarks of interest" constitute the information relayed to the computer.

Based on the above, the Board concludes that document D1 fails to disclose at least a specific software program wherein the functional images are processed and combined with the morphological image.

Hence, the subject-matter of claim 1 is novel over document D1.

8.2 Document D3 concerns a system for coordinating surgery which makes use of three-dimensional information from a radiolocalisation system involving gamma cameras (page 3, lines 6 to 10) combined with morphological images from a separate imaging system (paragraph bridging pages 9 and 10).

There is no disclosure in document D3 of a surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process.

The respondent's argument that the skilled person would read the disclosure of document D3 as implying a standard surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process cannot be accepted. Document D3 explicitly describes an imaging system that provides morphological images **in real time** using ultrasound or X-ray imaging (page 9, line 34 to page 10, line 11).

It follows that the subject-matter of claim 1 is novel over document D3, too.

8.3 Novelty of the subject-matter of claim 1 has not been questioned on the basis of the other cited documents. The Board does not see either how they could be relevant in this respect, since they do not disclose the provision of functional images within the meaning of claim 1.

8.4 Hence, the subject-matter of claim 1 is novel within the meaning of Article 54 EPC.

9. Inventive step

The teaching of document D1 concentrates on the provision of functional 3D images within the meaning of the claimed invention. It does not focus on the combination of images of different natures. Nor does it focus on surgical procedures.

As already mentioned above, document D3 directly concerns a system for coordinating surgery which makes use of three-dimensional information from a radiolocalisation system involving gamma cameras (page 3, lines 6 to 10) combined with morphological images from a separate imaging system (paragraph

bridging pages 9 and 10). More particularly, document D3 also discloses a specific software program, wherein functional images are processed and combined with a morphological image (page 14, lines 24 to 34). The appellant's argument that the gamma cameras of document D3 did not provide 3D functional images in real time within the meaning of claim 1 can be left aside. It remains that document D3 explicitly discloses to "overlay [...] an image" from a signal detector in the form of a gamma camera "on a real time [morphological] image of a separate imaging system". It follows that the disclosure of document D3 is closer to the claimed invention than that of document D1.

Hence, the Board agrees with the appellant that document D3 is the closest prior art.

As explained in paragraph 7.2 above, document D3 fails to disclose the feature of a surgical navigator providing a morphological CAT or magnetic resonance image obtained before the surgery process as claimed in claim 1.

CAT or magnetic resonance imaging techniques applied before a surgery process could provide a morphological image with a high degree of detail.

Hence, by virtue of the combination of such a morphological image with the functional images as claimed in claim 1, the problem of accurately controlling the surgical instruments so as to position them precisely with regard to the areas to be operated on is solved.

The Board agrees with the respondent that documents D2 and D6 disclose the provision of CAT or magnetic

resonance images obtained before a surgery process in order to coordinate it. The patent itself acknowledges that the provision of such images by a surgical navigator was generally known in the art (column 3, lines 1 to 6 and even claim 1). The appellant observed that document D1 (paragraph [0064]), too, disclosed that magnetic resonance imaging could be used to provide anatomic data for use by a surgical navigator.

However, document D3 stresses the importance of using real-time imaging technologies "for penetration path selection and real time monitoring of instrument insertion" (page 14, lines 24 to 34) so as to avoid "nerves and other sensitive structures such as blood vessels that could be damaged" by a surgical instrument (page 9, line 31 to page 10, line 2). Hence, it teaches away from the claimed differentiating feature.

It follows that the skilled person would not go against this teaching and would not implement the differentiating feature in the system of document D3.

As a consequence, the subject-matter of claim 1 is also inventive within the meaning of Article 56 EPC.

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 maintain the patent on the basis of:

   - claims 1 to 4 of the main request filed during the oral proceedings; and

   - description and figures of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated