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**D E C I S I O N**  
**of 13 June 2002**

**Case Number:** T 0799/01 - 3.2.2

**Application Number:** 94909815.6

**Publication Number:** 0684786

**IPC:** A61B 6/12

**Language of the proceedings:** EN

**Title of invention:**

Fiducial marker

**Applicant:**

Allen, George S.

**Opponent:**

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**Headword:**

-

**Relevant legal provisions:**

EPC Art. 52(1), 54, 56, 123(2)

**Keyword:**

"Novelty (yes, after amendment)"

"Inventive step (yes, after amendment)"

"New subject-matter (no)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0799/01 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 13 June 2002**

**Appellant:** Allen, George S.  
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**Representative:** Ede, Eric  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 27 February 2001  
refusing European patent application  
No. 94 909 815.6 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** W. D. Weiß  
**Members:** S. S. Chowdhury  
J. C. M. De Preter

## Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 27 February 2001 to refuse European patent application No. 94 909 815.6.

The ground of refusal was that claim 1 of the main and the auxiliary requests introduced subject-matter which went beyond the original disclosure of the invention, such that the amendments made in these claims did not meet the requirement of Article 123(2) EPC. The decision also referred to communications from the examining division, in which objections under Article 84 EPC and Article 52(1) EPC had been raised.

The examining division argued that the wording of claim 1 of both requests was such that it defined a single substance capable of being imaged by both CT imaging as well as MRI imaging, whereas the application as originally filed disclosed only two separate materials, one capable of being imaged by CT imaging and the other by MRI imaging.

The dependent claims also defined combinations of materials not originally disclosed.

In the communications prior to the refusal of the application, the examining division had cited the following documents:

D1: EP-A-0 146 699

D2: EP-A-0 591 712 (cited under Article 54(3) EPC)

D3: EP-A-0 427 358

The Board has also considered the document:

D4: US-A-4 991 579.

II. On 4 April 2001 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee. On 3 July 2001 a statement of grounds of appeal was filed.

III. Oral proceedings were held on 13 June 2002, at the end of which the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 37 submitted at the oral proceedings.

V. Independent claims 1, 2, and 37 read as follows:

1. "A fiducial marker assembly, the assembly comprising: an imaging marker (10) having a non-metallic housing (12) of a biocompatible material, the housing (12) including a cavity (14) containing a mixture of agents, wherein the mixture comprises two agents which constitute respective imaging materials for mutually different imaging modalities, and in that the respective centroids of said respective imaging materials are substantially coincident".

2. "A fiducial marker assembly, the assembly comprising: an imaging marker (10) having a non-metallic housing (12) of a biocompatible material, and doped with a first agent, the housing (12) further including a cavity (14) containing a second agent, wherein both agents each constitute respective imaging materials for mutually different imaging modalities, and in that the respective centroids of said respective

imaging materials are substantially coincident".

37. "A method for providing a fiducial marker having a non-metallic housing of a biocompatible material that is imageable under different imaging modalities, including computerized X-ray tomography and nuclear magnetic resonance imaging, wherein the marker has a single cavity for receiving imaging material comprising the steps of: providing the marker with a first imaging agent that is imageable under computerized X-ray tomography; and providing the cavity of the marker with a second imaging agent that is imageable under nuclear magnetic resonance imaging, wherein the centres of the regions of the fiducial marker that are defined by each imaging agent are coincident, thereby permitting the proper registration of images obtained by each imaging modality."

Claims 3 to 36 are dependent on claims 1 and/or 2.

VI. In its written submissions and at the oral proceedings the appellant argued as follows:

The present invention provided a significant technical advance over the prior art in that the present markers were compact by virtue of the coincidence of the respective centroids of the imaging materials. This improved patient comfort as well as accuracy of registration of the images taken in different imaging modes. Therefore, the claimed markers involved an inventive step.

The passage in document D4, column 7, lines 26 to 32, when read in isolation, might suggest the use of a mixture of agents in the cavity of a marker for imaging

in different imaging modalities, but when taken in the context of the entire disclosure, stated that only one agent was chosen for any one marker, and the entire tenor of this document was that one marker was exchanged for another marker if a different imaging modality was desired.

## Reasons for the Decision

1. The appeal is admissible since it complies with the provisions mentioned in Rule 65(1) EPC.
2. *Article 123(2) EPC*
  - 2.1 Claim 1 is based on claim 1 of the application as originally filed and includes the further features that the housing is **non-metallic**, the cavity contains **a mixture of at least two imaging agents**, and **the respective centroids of said respective imaging materials are substantially coincident** [Board's emphasis].

These amendments are supported by the application as originally filed as follows:

The last paragraph on page 11 of the description and the first paragraph on page 12 explain why solid metal is to be avoided, and an example of a non-metallic housing is given in original claim 10, for example.

The sentence linking pages 19 and 20 provides support for a mixture of more than two imaging agents.

Original claim 8 provides support for the feature that the centroid of the housing is substantially coincident with the centroid of the agent in the cavity. In the case where the housing is not used as an imaging agent then the fact that the agents are miscible means that their centroids are coincident (see original claim 29 and page 7, lines 28 to 31).

Therefore, claim 1 is allowable under Article 123(2) EPC.

2.2 The amendments to claim 1 also address the examining division's objection that led to the refusal of the application. Claim 1 defines a mixture of two agents, each of which constitutes a respective imaging material for mutually different modalities, thereby alleviating the problem that led to refusal of the application.

2.3 Claim 2 is based on claim 1 of the application as originally filed and includes the further features that the housing is **non-metallic**, the housing is **doped** with a first imaging agent, and **the respective centroids of said respective imaging materials are substantially coincident** [Board's emphasis].

The remarks relating to the non-metallic housing and the respective centroids of said respective imaging materials being substantially coincident, set out above with respect to claim 1 also apply to claim 2. That the housing is doped with a first imaging agent is supported by page 7, lines 18 and 19, and original claim 11, for example.

Therefore, claim 2 is allowable under Article 123(2) EPC.

2.4 Claim 37 is based on claim 41 as filed, with amendments that do not go beyond the amendments to claims 1 and 2, and this claim is equally allowable.

2.5 The dependent claims correspond to the dependent claims of the application as originally filed. Therefore, the amended claims meet the requirement of Article 123(2)EPC.

*Article 52(1) EPC*

3. *Novelty*

3.1 In its communication dated 8 October 1999, the examining division cited document D1 as being novelty destroying for the then pending claim 1, arguing that the imaging material disclosed therein, being a metal, was imageable by X-rays and also by ultrasound, and hence that it was imageable by two different imaging modalities. This document no longer anticipates the subject-matter of claim 1 since the housing cavity must now have a mixture of two different imageable agents whose centroids are coincident, which features are not disclosed in document D1.

This document also does not anticipate the subject-matter of claim 2 since the claimed housing is doped with a first imaging agent and has a cavity with a second imaging agent, the centroids of the imaging agents being coincident, which features are also not disclosed in document D1.

3.2 Of the various embodiments disclosed in document D2 (cited under Article 54(3) EPC) only those described with reference to Figures 2 and 3 disclose a housing



having a cavity for an imaging agent, the respective centroids of said respective imaging materials being substantially coincident. The housing may be metallic or non-metallic, and in the case of a non-metallic housing this is not doped, and the cavity does not enclose a mixture of at least two agents which constitute respective imaging materials for mutually different imaging modalities. Therefore, this document does not anticipate the subject-matter of any of claims 1, 2, or 37

- 3.3 Document D4 describes a fiducial implant detectable by an imaging system such as CT, PET, or NMR. One of the problems of prior art implants, stated in column 1, lines 58 to 64, is the inability to compare images obtained at different times or at the same time using different image modalities. It is stated in column 7, lines 26 to 32 that the implantable marker, which may be of titanium in the form of a hollow sphere, can be filled with agarose gel having various desired dopants.

Despite the impression these passages give that the housing may be filled with a mixture of dopants for different imaging modes, the Board accepts the appellant's submission that this document does not give a solution to the stated problem, and that the totality of the disclosure of this document indicates that the housing is filled with only a single agent capable of being imaged in a only single mode.

The reason for this is that the quoted passage in column 7 goes on to say that the **choice** of the dopant depends on the imaging system used to best accent or highlight the marker. This means that the marker is exchanged for another marker with a different agent if

a different imaging mode is desired. It is for this reason that the marker 12 is provided with a polygonal indentation 16 and is intimately connected to a second portion 14 for anchoring into the body (see column 7, lines 32 to 55), so that it may be easily screwed out and replaced by another marker should a different imaging mode be desired.

Therefore, document D4 does not disclose a doped housing or a housing cavity filled with a mixture of imaging agents.

The subject-matters of claims 1, 2, and 37 are novel, accordingly.

4. *Inventive step*

4.1 A problem associated with medical imaging techniques concerns the accurate selection and comparison of views of identical body areas in images that have been obtained by imagers at different times or by images obtained using different image modalities, e.g., CT, MRI, SPECT, and PET. It is necessary to establish a one-to-one mapping between points in the image and points on the anatomy, which is referred to as registering image space to physical space, and it is also necessary to register one image space to another image space. The goal of registering two arbitrarily oriented three dimensional images is to align the coordinate systems of the two images such that any given point in the scanned anatomy is assigned identical addresses in both images.

The ability to image under both CT and MRI, for example, with a given marker is useful since it enables

images derived from different imaging modalities to be registered. For example, the capability to register CT and MR images allows the integration of information concerning bony structure provided by a CT scan with the soft tissue anatomical information provided by an MRI scan.

4.2 The problem is, therefore, to construct a fiducial marker that can be used to accurately register image space onto image space across different imaging modalities or to accurately register image space onto physical space for performing image guided surgery or therapy. A further problem is that, with a view to patient comfort, the marker must be compact rather than extended.

4.3 The solution as defined in claim 1 is to provide a non-metallic housing of a biocompatible material with a cavity containing a mixture of agents which constitute respective imaging materials for mutually different imaging modalities, wherein the respective centroids of the respective imaging materials are substantially coincident.

The solution as defined in claim 2 is to provide a biocompatible non-metallic housing doped with a first agent which constitutes one imaging material and defining a cavity containing a second agent which constitutes another imaging material, wherein the respective centroids of the respective imaging materials are substantially coincident.

The claimed markers are imageable under at least two different imaging modalities, without having to be exchanged by a different marker, and are compact by

virtue of the coincidence of the centroids of the imaggable materials.

The method of claim 37 covers both of claims 1 and 2, and also contains the above solutions.

#### 4.4 The closest prior art

Document D3 discusses the possibility of comparing images from different imaging modalities (column 1, lines 27 to 37) and mentions the use of fiducial implants that are identifiable by different imaging systems. However, no constructional details of the implants are given.

Document D4 discusses the possibility of comparing images at different times and from different imaging modalities and mentions the use of fiducial implants that are identifiable by different imaging systems (column 5, lines 35 to 38 and column 6, lines 33 to 37). There are references to taking scans from different image modalities at the same time (for example column 1, lines 61 to 64) and also to taking scans at different times (for example column 3, lines 21 to 27). This document also provides some detail of the construction of the markers, with reference to Figures 1a to 1c. Therefore, this is the closest prior art.

4.5 However, as discussed above, this document does not suggest the possibility of using one and the same implant for use in different imaging modalities. Nor does any of the other cited documents suggest such a possibility. The present application, therefore, breaks

new ground in suggesting this possibility.

Not only is the suggestion new but the solutions as defined in claims 1, 2, and 37 are also not known or suggested in the prior art. In particular the use of a doped non-metallic housing instead of a metallic housing is not known, nor is it known to use a mixture of agents in the cavity of a housing for different imaging modes.

- 4.6 The fiducial marker assembly of claims 1 and 2, and the method of claim 37 involve an inventive step, accordingly.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the following basis:
  - Claims 1 to 37 submitted at the oral proceedings,
  - Figures as filed,
  - Description still to be adapted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß