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D E C I S I O N
of 28 October 2004

Case Number: T 1036/02 - 3.4.1

Application Number: 97107325.9

Publication Number: 0804943

IPC: A61N 5/10

Language of the proceedings: EN

Title of invention:
System and method for verifying the amount of radiation delivered to an object

Applicant:
SIEMENS MEDICAL SYSTEMS, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 56

Keyword:
"Added subject-matter (no - main request; yes - auxiliary requests I, II, III)"
"Inventive step (no - main request)"
"Admissibility of late filed requests (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1036/02 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 28 October 2004

Appellant: SIEMENS MEDICAL SYSTEMS, INC.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 March 2002 refusing European application No. 97107325.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, received on 22 May 2002, against the decision of the examining division, dispatched on 27 March 2002, refusing European patent application No. 97 107 325.9 (publication number 0 804 943). The fee for the appeal was paid on 22 May 2002. The statement setting out the grounds of appeal was received on 24 July 2002.

The examining division refused the application on the ground that claim 1 contained subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

II. In a communication accompanying the summons to oral proceedings, the Board referred, *inter alia*, to the following prior art document:

D1: WO-A-94/28971

III. Oral proceedings were held on 28 October 2004.

IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Main Request:

Claims: 1 to 8 filed on 28 September 2004,

Description: pages 1 and 4 to 12 as originally filed, pages 2, 3 and 3a filed on 9 May 2001,

Figures: 1 to 5, 7 and 8 as originally filed, 6 and 9 filed on 24 July 2002;

Auxiliary Request I:

Claims: 1 to 7 filed on 28 September 2004,

Description and **Figures** as for the main request;

Auxiliary Request Ia:

Claims: 1 to 7 filed in the oral proceedings on 28 October 2004;

Auxiliary Request II:

Claims: 1 to 5 filed on 24 July 2002 as Auxiliary Request I;

Auxiliary Request III:

Claims: 1 to 7 filed on 24 July 2002 as Auxiliary Request II;

Auxiliary Request IV:

Claims: 1 to 3 filed in the oral proceedings on 28 October 2004;

V. The wording of claim 1 of the **main request** reads as follows:

"*1. A system for verifying radiation dose delivered to an object, the system comprising:*

a radiation source (20) adapted to generate an output beam (1) directed to the object (13) and

detector means (91) arranged beneath said object (13) from the viewpoint of the output beam source and capable of measuring radiation exiting from said object (13) and caused by said output beam passed through said object and capable of generating exit radiation signals,

characterized by

processing means (18) for reverse calculating the radiation dose delivered to the object (13) based on said exit radiation signals and attenuation factors of said object."

VI. The wording of claim 1 of **auxiliary request I** reads as follows:

"1. A system for verifying radiation delivered to an object, the system comprising: a radiation source (20; 602) adapted to generate an output beam (1) directed to the object (13) and

detector means (91; 600) arranged beneath said object (13) from the view point of the output beam source and capable of measuring radiation exiting from said object (13) and caused by said output beam passed through said object and capable of generating exit radiation signals,

characterized by

processing means (18) adapted:

- for calculating an incident beam from the radiation source (602) using the exit radiation measured by the detecting means (91) and attenuation factors of the object (13) and

- for generating a delivered radiation map based on the incident beam and the attenuation factors."

The wording of claim 1 of **auxiliary request Ia** reads as follows:

"1. A system for verifying radiation delivered to an object, the system comprising:

a radiation source (20; 602) adapted to generate an output beam (1) directed to the object (13) and

detector means (91; 600) arranged beneath said object (13) from the view point of the output beam source and capable of measuring radiation exiting from said object (13) and caused by said output beam passed through said object and capable of generating exit radiation signals,

characterized by

processing means (18) adapted:

- for calculating an incident beam from the radiation source (602) using the exit radiation measured by the detecting means (91), attenuation factors of the object (13) and positional information of the relative position of the object to the radiation source (602) and

- for generating a delivered radiation map based on the incident beam and the attenuation factors."

VII. The wording of claim 1 of **auxiliary request II** reads as follows:

"1. A system for verifying radiation delivered to an object comprising:

a radiation source (20) adapted to generate an output beam (1) directed to said object (13), and

detector means (91; 600) disposed such that said object (13) is between said radiation source and said detector means, and capable of measuring radiation exiting from said object (13) as a result of said output beam,

characterized by

processing means (18) for determining an amount of radiation (610) delivered to two or more areas of said object based on measured exit dose values and on attenuation factors of two or more anatomical structures (620, 621, 622) respectively corresponding to the two ore [sic] more areas, and

output means (70,80) for outputting an amount of radiation (700; 840; 900) delivered to each of the two ore [sic] more areas in comparison with an amount of radiation (720) planned for delivery to each of the two or more areas."

VIII. The wording of claim 1 of **auxiliary request III** reads as follows:

"1. A system for verifying radiation delivered to an object comprising:

a radiation source (20) adapted to generate an output beam (1) directed to said object (13), and

detector means (91; 600) disposed such that said object (13) is between said radiation source and said detector means, and capable of measuring radiation exiting from said object (13) as a result of said output beam,

characterized by

processing means (18) for reverse calculating a delivered radiation dose map (610) with data of the amounts of radiation delivered to two or more areas of said object, said reverse calculation being based on measured exit dose values and on attenuation factors of two or more anatomical structures (620, 621, 622) respectively corresponding to the two ore [sic] more areas, and

output means (70, 80) for outputting the delivered radiation dose map (700, 840, 900)."

IX. The wording of claim 1 of **auxiliary request IV** reads as follows:

"1. A system for verifying radiation delivered to an object, the system comprising:
a radiation source (20) adapted to generate an output beam (1) directed to the object (13) and detector means (91) arranged beneath said object (13) from the viewpoint of the output beam source and capable of measuring radiation exiting from said object (13) and caused by said output beam passed through said object, said detector means being capable of generating exit radiation signals,
characterized by
processing means (18) for calculating the radiation exiting from said object (13) based on a planned radiation to be delivered to said object and attenuation factors of said object and means for enabling a comparison of the calculated radiation exiting from said object with the measured radiation exiting from the object."

X. The appellant's arguments can be summarised as follows:

Main Request

The original description (page 7, lines 1 to 7) specified that the detector unit was capable of measuring the radiation exiting an object. The amount of radiation exiting this object (*ie* the **exit dose information**) could be used to verify the radiation treatment. Thus, the detector unit within a portal imaging system was used to gather the patient's exit dose information from which the **delivered radiation dose** was then reverse calculated by the CPU. This general description of the basic idea of the invention, *i.e.* to base the incident beam on exit radiation signals alone, had been clearly originally disclosed also by original claim 1. Claim 1 according to the **main request**, which was limited with respect to the original claim 1 by including in addition a reference to the attenuation factors did not extend beyond the content of the application as filed and therefore did not violate Article 123(2) EPC.

Document D1 described a system combining a high-energy radiation therapy device with a tomographic imaging device. The tomographic imaging system produced a tomographic image of the patient for treatment planning purposes prior to radiation therapy. During the radiation therapy treatment, however, the radiation dose actually absorbed by the patient was not monitored. Though D1 also foresaw that a high-energy detector array could be added for verification purposes, it failed to disclose what information would be derived from this detector and did not suggest that a reverse

calculation of the radiation dose delivered to the patient could be based on the exit signals from this detector. The skilled person would only understand from this disclosure that the purpose of the high-energy detector was to verify the shape of the radiation beam.

Auxiliary Requests I, Ia, II, III and IV

Although some of the amendments in claims 1 according to the auxiliary requests were not explicitly disclosed in the original application documents, a highly-qualified person skilled in the technical field of high-energy radiation therapy systems would find them directly and unambiguously derivable from the application as filed.

Reasons for the Decision

1. The appeal is admissible.

Main Request
Article 123(2) EPC

2.1 Claim 1 according to the main request corresponds to the independent claim which the examining division decision regarded as comprising undisclosed subject-matter (Article 123(2) EPC). With respect to the findings of the examining division, the Board acknowledges that the application as originally filed does not **explicitly** disclose the following feature of claim 1:

"*processing means (18) for reverse calculating the radiation dose delivered to the object (13) based on said exit radiation signals and attenuation factors of said object*".

In other words, the original application documents do not explicitly teach that the reverse calculation of the **radiation dose** is based on the measured exit radiation **and** on the **attenuation factors** of the irradiated object, but only that the reverse calculation of the "*the delivered radiation map*" is based on such parameters (*cf.* claim 2 as originally filed).

2.2 However, in the Board's opinion, a person skilled in the art of high-energy radiation therapy systems, reading the application as originally filed, would understand that the "*reverse calculation*" not only of a "*delivered radiation map*" but also of the "*radiation dose*" delivered to the object necessarily implies the knowledge and the use of the object's attenuation factors and of their distribution within the irradiated volume (see *e.g.* application as published, column 5, lines 10 to 15 and *c*olumn 6, lines 38 to 45). In fact, it is generally known in the art that the radiation absorbed by an object is dependent both on the radiation source and on the object's characteristics (*e.g.* absorption factors).

2.3 Thus, the Board concludes that claim 1 of the main request is admissible under Article 123(2) EPC.

Inventive Step

3.1 D1 (see Figures 2, 2A and 8), which is considered to represent the closest prior art document, shows a radiation therapy system comprising, *inter alia,* a high-energy radiation source (32) for irradiating tumours in a patient's body and a primary barrier (107) subtending and occluding each ray exiting the patient. Both the radiation source and the primary barrier are mounted on a rotatable gantry. A tomographic imaging system (63), also mounted on the same gantry, employs a less powerful x-ray source (28) and a detector array (32) to produce a tomographic image of the patient, thereby allowing verification of the patient's position just prior to the radiation therapy treatment. In addition, a high-energy detector array (105) may also be placed on the internal surface of the primary barrier (107) to receive the radiation from the high-energy radiation source (32) which has passed through the patient's body, in order to verify that the planned radiation dose is properly delivered to the patient (see page 13, lines 21 to 23 and page 18, lines 25 to 30). However, D1 does not specify how the high-energy detector array (105) would be used for monitoring the radiation therapy treatment.

3.2 The subject-matter of claim 1 thus differs from the system known from D1 in that it further comprises the following feature recited in the claim's characterizing portion:

- processing means for reverse calculating the **radiation dose delivered** to the object based on

said **exit radiation signals** and **attenuation factors** of said object.

3.3 D1 is not directly concerned with the determination of the radiation dose **delivered** to the patient during a radiation treatment. However, it points out that the control of the radiation therapy machine involves "*the definition of a desired dose map 75*" (page 21, line 21). Such a map *"may be most easily entered by displaying the tomographic image of each slice of a patient on the display 71 or the terminal 70 and manually tracing around the tumorous area 76 using a track-ball or similar input device as is well understood in the art. Standard area-filling computer programs may be used to transfer the dose values assigned to each traced region to the appropriate element in the array of memory representing the desired dose map 75" (*see page 21, lines 17 to 30, and Figures 9A to 9D).

As the attenuation of the medium affects the fractional contribution of the total energy released per unit mass ("terma") from the beams at different incident angles, in cases where accurate calculation of the radiation dose is critical, the dose distribution should be calculated separately for each beam *"based on the attenuation of overlying voxels, such attenuation deduced from the parameters of the tomographic image"* (D1, page 25, line 32 to page 26, line 4).

In other words, D1 covers the following aspects of a radiation therapy treatment which are relevant for the assessment of the inventive step of the claimed subject-matter:

– the need to specify the **radiation dose** to be delivered to certain areas of the patient's body;

– the possibility of verifying on the basis of the radiation exiting the patient's body and detected by a high-energy detector that the planned radiation dose has actually been delivered; and

– the fact that the attenuation of a radiation beam passing through an object (*i.e.* its absorption by the object) can be evaluated on the basis of known parameters.

3.4 In the light of the teaching of D1, the Board considers that it would be obvious to the skilled person referred to above (see item 2.2) to add to the radiation therapy system known from D1 means for verifying that the planned radiation dose was correctly delivered. Such a skilled person would rely on processing means for calculating the radiation dose delivered to the object on the basis of exit radiation signals, which could be provided by the high-energy detector array, and of the object's characteristics (*i.e.* attenuation factors). In doing so, the person skilled in the art would arrive at a system falling within the terms of claim 1 of the main request.

3.5 Hence, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

Auxiliary Request I

4.1 Claim 1 according to **auxiliary request I** specifies that the processing means is adapted:

– for calculating an incident beam emitted by the radiation source using the exit radiation measured by the detecting means and attenuation factors of the irradiated object; and

– for generating a delivered radiation map based on the incident beam and the attenuation factors.

4.2 The above features find no support in the application as filed which only discloses processing means for calculating the radiation delivered to (*i.e.* absorbed by) the object, not the incident beam. The same applies to the delivered radiation map being generated based on the incident beam and the attenuation factors.

4.3 Hence, claim 1 of auxiliary request I is not admissible under Article 123(2) EPC.

Auxiliary Request II

5.1 Claim 1 according to **auxiliary request II** specifies, *inter alia*, that the processing means determines an amount of radiation delivered to **two or more** areas of said object based on measured exit dose values and on attenuation factors of **two or more** anatomical structures respectively corresponding to the two or more areas. Similarly, the output means outputs an amount of radiation delivered to each of the two or

more areas in comparison with an amount of radiation planned for delivery to each of the two or more areas.

5.2 The definition of the processing means and of the output means with respect to two or more areas corresponding to two or more anatomical structures constitutes, in the Board's opinion, an arbitrary selection not supported by the application as filed. The original application only contained embodiments showing three (see Figures 2 to 7 and 8b) or seven (see Figure 9) such structures. Thus, the value "*two*" is not disclosed in the original application, and moreover, the expression "*two or more*" implies a purposive exclusion of "*one*" which cannot be clearly and unambiguously derived from the application as filed.

5.3 Accordingly, the subject-matter of claim 1 of auxiliary request II infringes Article 123(2) EPC.

Auxiliary Request III

6. Since claim 1 according to **auxiliary request III** also refers to "*two or more areas*" of the object, the same reasoning as for auxiliary request II leads to the same conclusion that this claim is not admissible under Article 123(2) EPC.

Auxiliary Requests Ia and IV
Admissibility of late-filed requests

7.1 These requests were submitted in the oral proceedings held on 28 October 2004, *i.e.* at a very late stage in the proceedings.

7.2 Claim 1 according to **auxiliary request Ia** states that the processing means are adapted for calculating **an incident beam** emitted by the radiation source using the exit radiation measured by the detecting means, attenuation factors of the irradiated object and **positional information** of the relative position of the object to the radiation source. As there is no support in the application as filed for processing means calculating the **incident** beam or for positional information being taken into account in the calculation, the subject-matter of claim 1 of auxiliary request Ia infringes Article 123(2) EPC.

The system of claim 1 according to **auxiliary request IV** comprises means for enabling a comparison of the calculated radiation exiting from the object with the measured radiation exiting from the object. Such means, however, are not disclosed in the original application (Article 123(2) EPC).

7.3 As the late-filed auxiliary requests Ia and IV cannot be regarded as clearly allowable, the Board exercises its discretion not to admit them into the appeal proceedings.

8. In conclusion, the Board finds that none of the appellant's requests is allowable and that the present application has to be refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Davies