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D E C I S I O N
of 29 July 2005

Case Number: T 1095/03 - 3.4.1

Application Number: 97113657.7

Publication Number: 0810005

IPC: A61N 5/10

Language of the proceedings: EN

Title of invention:
Radiation therapy system

Patentee:
WISCONSIN ALUMNI RESEARCH FOUNDATION

Opponent:
Siemens AG

Headword:
Radiation therapy system

Relevant legal provisions:
EPC Art. 100(a), 54(1)(2), 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 1095/03 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 29 July 2005

Appellant:
(Opponent)

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Representative:

Mocker, Wolfgang

Respondent:
(Proprietor of the patent)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 21 July 2003
rejecting the opposition filed against European
patent No. 0810005 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: B. J. Schachenmann
Members: H. K. Wolfrum
M. G. L. Rognoni

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 21 July 2003, rejecting the opposition against European patent No. 0 810 005. The notice of appeal was received on 22 September 2003. The prescribed fee was paid on the same day. On 19 November 2003 a statement of grounds of appeal was filed.
- II. Pursuant to Article 100(a) EPC, the opposition was based on the grounds of lack of novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC).
- III. Oral proceedings before the Board of Appeal were held at the request of the parties on 29 July 2005.
- IV. The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent (patent proprietor) requested, as a main request, that the appeal be dismissed and the patent maintained as granted. As an auxiliary measure the respondent requested the maintenance of the patent in amended form on the basis of four sets of claims according to auxiliary requests 1 to 4 filed on 29 June 2005.

- V. During opposition and in the appeal the appellant made reference to the following documents:

D1: EP-A-0 382 560;

D2: EP-A-0 113 879; and

D3: EP-A-0 464 645.

VI. Independent claim 1 of the respondent's **main request** reads as follows:

"1. A radiation therapy machine having a radiation source (32) directing a radiation beam (26) toward a patient with a treatment volume at a plurality of angles within a gantry plane, the beam including a plurality of adjacent rays diverging about one central ray, the beam, when not occluded, subtending a radiation window (33) on the patient, the radiation machine comprising:

a patient support means (11) disposed along an axis of translation for supporting a patient and for moving the patient along the axis of translation; and

a motivation means for moving the radiation source (32) around an axis of rotation during motion of the table along the axis of translation;

whereby, the central ray sweeps a helical path through the patient."

Claims 2 to 8 are dependent claims.

VII. The appellant essentially relied on the following submissions:

A radiation therapy machine having all the features as specified in claim 1 of the patent as granted was known from document D1. The known machine had in particular a patient support means which was movable along a translation axis and a motivation means for a rotating movement of the radiation source around an axis of rotation (coincident with the axis of translation). Thus the only question remaining was whether it was foreseen to operate the known machine by a combined

continuous translation of the patient support means and rotation of the motivation means. In this respect, D1 repeatedly provided information relating to such a combined continuous movement of the patient support means and the motivation means so that the known radiation therapy machine did not only possess the ability for a helical sweeping of the radiation beam but made in fact use thereof. In a specific embodiment D1 showed a so-called third generation CT-scanner, which, in distinction to first and second generations scanners, did not require an intermittent rotation of the radiation source and translation of the patient support.

If, however, simultaneous control of a rotation of the radiation source with the translation of the patient support and the resulting helical path of the radiation beam was not considered to be disclosed by document D1, this feature was at any rate known in the context of a CT-scanner from each of documents D2 and D3. Since the skilled person at the priority date had an overview of the field of radiation therapy machines as well as that of CT-scanners and since in particular document D2 promised a shortening of the treatment time by the helical scanning of the radiation beam, it would have been obvious for the skilled person to make use of the advantage known from D2 in the therapy machine according to D1. This was all the more true as D1 expressly mentioned that the invention which it described could be designed to be retrofitted to existing diagnostic CT-scanners.

For these reasons the subject-matter of claim 1, if it were considered novel, did not involve an inventive step.

VIII. The respondent's submissions may be summarised as follows:

As regards novelty, the passages cited by appellant from D1 were consistent with second and third generation systems in operation without involving a helical path of the radiation beam. As far as a motion of the table supporting the patient was mentioned in D1, this meant only slight positional adjustments which became necessary in the context of a variation of the gantry tilt. Moreover, the apparatus known from D1, being a retrofitted CT-scanner, was equipped with a low dose radiation source so that an efficient therapy required a scanning of the area to be treated through multiple cycles. However, such multiple rotation arrangements as taught by D1 were incompatible with helical irradiation arrangements.

Because of this incompatibility, the mere existence of helical CT-imaging in documents D2 and D3 would not incite a skilled person to adopt helical arrangements in the therapy apparatus according to document D1. The teaching of D1 was in fact about converting a CT-scanner to a device which allowed for simultaneous imaging and therapeutic treatment and was based on selecting by masking a narrow beam for treatment from a wide imaging beam. Due to the different widths of the imaging beam and the therapeutic beam, it was impossible to advance both beams simultaneously in a helical movement and to obtain at the same time a

smooth coverage of the irradiated object by both beams. Therefore, an apparatus resulting from a combination of the teaching of D1 with that of any one of documents D2 or D3 would not work without further modifications, not envisaged by any of the prior art documents. Furthermore, none of the available prior art documents was concerned with the problem underlying the present patent, *i.e.* of avoiding gaps or hot spots inherent in radiation therapy on a slice-by-slice basis.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

2. *Novelty of the subject-matter of the main request*
 - 2.1 Document D1 (see in particular Figure 1 and the corresponding description) refers to a combined CT-scanner/radiation therapy machine having a common radiation source for imaging and therapeutic treatment of a patient. The radiation source is mounted on a gantry for irradiating the treatment volume at a plurality of angles within the gantry plane and the machine is thus equipped with motivation means for moving the radiation source around an axis of rotation. The radiation beam for full area cross-sectional imaging is shaped by an aperture in an attenuating masking member for therapeutic irradiation so as to include a plurality of adjacent rays diverging about a central ray and subtend a radiation window on the patient. The patient is supported on a support means

constituted by a table which is disposed along an axis of translation and capable of moving the patient along the axis of translation. The axis of translation and the axis of rotation may be parallel to each other.

2.2 It is in dispute between the parties whether document D1 discloses a radiation therapy machine equipped with means for a therapeutic treatment by simultaneously rotating the motivation means and translating the patient support means so that the radiation beam would follow a helical path through the patient.

2.3 The appellant sees support for a combined rotation of the radiation source and translation of the patient table during therapy in particular in the following pieces of information provided in the disclosure of D1:

column 7, lines 10 to 14: *"Without patient motion, repeatedly scan a large number of times with or without varying gantry tilt and/or slight table motion, according to the therapeutic prescription."*

column 12, lines 18 to 29: *"The present invention calculates geometrically the masking member aperture required in each scanner orientation to irradiate the target lesion as the scanner rotates, (and also the table motion, gantry tilt, and masking member aperture required, if three-dimensional radiotherapy is used). The computer can then control the treatment process by adjusting the x-ray output, masking member aperture, table position, and gantry tilt as required to achieve the prescribed treatment to the target lesion area."*

2.4 The Board notes that the cited passages in D1 mention a motion of the scanner table in the context of a variation of the gantry tilt. Such a motion is not necessarily a translation along an axis coextending with the axis of rotation of the radiation source. In fact, as is explained in column 13, lines 32 to 39, and confirmed in column 6, lines 46 to 53, of D1, the scanner table can be moved up or down as well as in or out, and thus laterally with respect to the axis of rotation, in order to accommodate the patient position for each gantry tilt angle and moving the target region within the isocenter of rotation.

Moreover, whenever D1 refers to concrete modes of scanning, it specifically mentions translate-rotate geometry CT-scanners, for which rotation of the radiation source and translation of the target area occur in an alternating fashion, or purely rotational scanners (see column 13, lines 40 to 49, and column 15, lines 8 to 14). Furthermore, by relating the size of the opening in the masking member to the usual slice thickness of a standard collimator found in a CT-scanner (column 8, lines 18 to 21) and by referring to variable imaging slice thicknesses (column 11, lines 15 to 22), the description of the known therapy machine evokes for the skilled reader an operation on a slice-by-slice basis.

2.5 Consequently, document D1 and in particular the cited passages do not disclose in a clear and unambiguous manner the option of therapeutic scans by simultaneously rotating the radiation source and translating the patient support.

Documents D2 and D3 disclose CT-scanners only and do not relate to radiation therapy machines.

Therefore, the subject-matter of claim 1 of the patent as granted is new within the meaning of Articles 52(1) and 54(1) and (2) EPC with respect to the teachings of the cited prior art documents.

3. *Inventive step of the subject-matter of the main request*

3.1 A combined simultaneous rotation of the radiation source and translation of the patient support so that the radiation beam follows a helical path through the body of a patient is known for imaging purposes in CT-tomography scanners from each of documents D2 (see claim 1; Figures 1, 2 and 9) and D3 (see column 1, line 51, to column 2, line 4; Figures 1 to 5). Document D2 in particular presents helical scanning as a means for shortening the data acquisition time with respect to an imaging of the object on a slice-by-slice basis (page 1, line 20, to page 2, line 11; page 2, lines 21 to 26; and page 14, lines 4 to 10).

3.2 Hence, the decisive question to be answered is whether the skilled person in the technical field at issue would have considered to implement a helical scanning known from diagnostic machines also in a therapy machine known from document D1 considered as the closest prior art.

3.3 Radiation therapy presupposes reliable tomography for diagnosis and therapy planning and radiation therapy machines are conventionally equipped with imaging means

so as to allow a precise control of the position of the patient with respect to the source of radiation. Hence, a skilled person concerned with the development of radiation therapy machines can be expected to possess technical knowledge in the field of diagnostic CT-scanners as well.

Therefore, it can be assumed that the skilled person has been aware not only of the teaching of document D1 but also of that of documents D2 and D3.

- 3.4 Nevertheless, as was convincingly argued by the respondent, helical therapeutic scanning cannot be readily implemented in the type of radiation therapy machine known from document D1.

A basic feature of the machine known from D1 is its capability of simultaneously performing radiation therapy and CT-imaging (see in D1: column 2, lines 49 to 54; column 7, lines 19 to 28; column 9, lines 26 to 51) from the same radiation source. It is in this context that the indication, relied on by the appellant, in column 13, lines 22 to 23: "*The present invention can be designed to be retrofitted on existing diagnostic CT scanners.*" has to be seen. An operational constraint associated with this functionality concerns the intensity of the radiation beam. Radiation therapy requires beam intensities which are orders of magnitude higher than those which are useful for the CT imaging detectors (*ibid.* column 11, lines 23 to 26; column 15, lines 1 to 7). These conflicting requirements for a machine which combines therapy and imaging from the same radiation source cannot be fully overcome by the provision of radiation sources of higher dose for

therapy and compensating masking members for imaging. Therefore, the known machine uses radiation sources having dose rates compatible with imaging requirements and compensates for the comparatively low dose by multiple therapeutic scanning for the treatment of a given target lesion (*ibid.* column 11, lines 27 to 32). According to a specific example, a treatment might consist of 100 or more therapeutic scans of the target area (*ibid.* column 11, lines 32 to 36; column 13, lines 22 to 31). Whilst such multiple scanning is readily implemented with a treatment of an extended target lesion on a slice-by-slice basis, it would indeed not be meaningfully combined with a helical scanning of the target lesion since it would require, in addition to the multiple rotations of the radiation source, multiple translations of the patient support along the full extension of the target lesion. In particular, the speed of treatment could hardly be improved thereby.

Moreover, as pointed out by the respondent, due to the different widths of the imaging beam and the therapy beam, the pitch of both beams would differ for a helical scanning movement so that gaps between the therapeutically treated areas or overlaps of the imaged areas would occur.

- 3.5 In this context, the appellant's submission that D1 in column 13, lines 1 to 7, explicitly mentioned the alternative of performing radiation therapy without simultaneous CT-imaging and that in such a case no incompatibilities with helical scanning could arise, is not found convincing.

Although D1 teaches that, if desired, therapy can be performed without imaging, a machine without the capability of simultaneous imaging and therapy is not what, in the Board's view, a skilled reader actually learns from the teaching of document D1.

- 3.6 For the above reasons, even assuming that the skilled person has been aware of helical tomographic CT-scanning for which the rotation of the radiation source is combined with the translation of the patient support, he would not have considered helical scanning to constitute a practically viable mode for therapeutic scanning in the specific radiation therapy machine disclosed by document D1 and thus would not have combined the teaching of document D1 with that of D2 or D3.

In conclusion, the subject-matter of claim 1 under consideration does not follow in an obvious manner from the prior cited by the appellant. Therefore, the claimed subject-matter is to be considered to involve an inventive step within the meaning of Articles 52(1) and 56 EPC.

4. In summary, the grounds of opposition under Article 100(a) relied on by the appellant do not prejudice the maintenance of the patent as granted.

Having found the respondent's main request allowable, there was no reason to deal with any of the auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

B. Schachenmann