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**Datasheet for the decision
of 22 June 2023**

Case Number: T 2093/19 - 3.4.01

Application Number: 15161820.4

Publication Number: 3075415

IPC: A61N5/10

Language of the proceedings: EN

Title of invention:

METHOD, COMPUTER PROGRAM AND SYSTEM FOR DOSE CALCULATION IN
RADIOTHERAPY

Patent Proprietor:

RaySearch Laboratories AB

Opponent:

PTW Benelux B.V.

Headword:

Dose calculation in radiotherapy / PTW Benelux

Relevant legal provisions:

EPC Art. 52(1), 54

EPC R. 80

RPBA Art. 12(4)

RPBA 2020 Art. 25(2)

Keyword:

Novelty - main request (no), first auxiliary request (no)

Amendment occasioned by ground for opposition - first auxiliary request (yes)



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Case Number: T 2093/19 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 22 June 2023

Appellant: PTW Benelux B.V.
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 29 May 2019 rejecting the opposition filed against European patent No. 3075415 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chair P. Scriven
Members: T. Petelski
R. Winkelhofer

Summary of Facts and Submissions

- I. The European patent was opposed based on grounds of opposition under Article 100(a) and (b) EPC. During opposition proceedings, the opponent submitted, *inter alia*, documents D1 to D5.
- II. The Opposition Division rejected the opposition, considering that the invention was sufficiently disclosed and that the claims of the patent were novel and involved an inventive step in view of D1 to D5.
- III. The opponent appealed this decision and requested that it be set aside and that the patent be revoked. They also unconditionally requested oral proceedings.
- IV. In their reply to the appeal, the proprietor requested that the appeal be dismissed (main request) or the patent maintained on the basis of one of three auxiliary requests, filed during opposition proceedings and re-filed with the reply to the appeal.
- V. The admission of the auxiliary requests has been challenged by the opponent.
- VI. In its preliminary opinion, the Board, amongst other things, found claim 1 of the main and first auxiliary requests to lack novelty over

D3: EP 1 778 353 B1.

VII. During oral proceedings before the Board, the proprietor withdrew their second and third auxiliary requests.

VIII. Claim 1 of the main request reads:

A method of dose calculation for radiotherapy involving

a. providing a planning image of a portion of a body to be subjected to radiotherapy,

b. providing a fraction image of the same portion, and

c. registering (S2) the planning image with the fraction image to produce a deformation field for the planning image, and using the deformation field to obtain a first basis for calculation comprising first location information and first material property information related to the portion, the method comprising the steps of

d. obtaining a second basis for calculation based on the fraction image (S3), comprising second location information and second material property information related to the portion, and

e. performing (S5) dose calculation based on the first basis for calculation and the

second basis for calculation and using material property information from the first and the second basis for calculation.

IX. Claim 1 of the first auxiliary request reads (amendments with respect to claim 1 of the main request are highlighted by the Board):

A method of dose calculation for radiotherapy involving

a. providing a planning image of a portion of a body to be subjected to radiotherapy,

b. providing a fraction image of the same portion, and

c. registering (S2) the planning image with the fraction image to produce a deformation field for the planning image, and deforming the planning image using the deformation field to obtain a first basis for calculation comprising first location information and first material property information related to the portion, the method comprising the steps of

d. obtaining a second basis for calculation based on the fraction image (S3), comprising second location information and second material property information related to the portion, said second location information and second material property information taken from the fraction image, and

e. performing (S5) dose calculation based on the first basis for calculation and the second basis for calculation and using material property information from the first and the second basis for calculation, wherein the dose calculation is performed using material property information from the first basis for calculation in at least a first region of the portion of the body and material property information from the second basis for calculation in at least a second region of the portion of the body, which is different from the first region.

Reasons for the Decision

The invention

1. The invention concerns dose calculation for radiotherapy treatment of a target, such as a tumour ([0001], [0002] of the patent). Typically, an initial treatment plan, which includes dose calculation, is made based on a computed-tomography (CT) planning image. The treatment plan is updated based on fraction images, taken before each fractional treatment ([0003] - [0006]). The invention proposes not only to use the geometric contour information from the fraction image for updating the dose calculation, as was known in the prior art, but also to use material property information from the fraction image. This allows variations in tissue density, that may have occurred

over the course of the treatment, to be taken into account ([0010], [0011], [0013]).

Main request - novelty over D3

2. D3 relates to adaptive treatment planning for considering "changes in the size, shape, or other characteristics of the tumor or of organs at risk" (D3, [0004] - [0006]). The planning image is a high-resolution CT image ([0020], [0021]). Contours of a tumour and organs at risk are determined by a contouring processor and stored in a "contours memory". "Other anatomical data ... such as radiation attenuation or tissue density information" are also stored in the contours memory ([0018]). These data are used for calculating an optimized initial treatment plan ([0018] and [0019]; see also [0029]).
3. The initial treatment plan is adapted, during each fractional treatment, based on treatment images of lower resolution ([0023] and [0024]). These treatment images correspond to what the patent calls "fraction images". Before each fractional treatment, the current treatment image is registered with the planning image. Depending on the deformations required for registering, the contours stored in the contours memory are updated, and the treatment plan is adapted accordingly ([0025], [0026] and [0032]).
4. According to the proprietor, the subject-matter of claim 1 differed from D3 in the following:
 - (a) D3 did not relate to dose calculation. Rather, an initially determined dose was kept throughout the treatment and never changed. Only beam parameters,

such as beam angles and collimator settings, were updated based on a treatment image.

- (b) D3 disclosed no dose calculation at all that took into account material property information from the treatment image. In D3, it was only the geometric (deformation) information, derived from the treatment images, that was used in updating the beam parameters, as emphasized in paragraph [0034]: "the treatment images are not used to extract information on radiation attenuation or tissue density for calibrating the treatment plan". The immediately following sentence, in brackets, referred vaguely to tissue density information but did not specify what this information was used for, or why or how it was used. The bracketed sentence also contradicted the other parts of D3 and failed to indicate what should be done if the treatment images were not taken by a CT scanner. Hence, this sentence could not disclose the use of tissue density information from treatment images as a basis for any kind of calculation.

5. The Board, however, cannot recognise these differences.
6. To the person skilled in the planning of radiation treatment, "dose calculation" means any calculation involving the dose of radiation delivered to the target location, in consideration of the beam configuration (angles, intensity, shape, etc.) and the penetrated tissue (geometry, density, atomic composition). It can be, for example, the calculation of the dose required for a medical effect, or the calculation of the beam parameters needed to deliver some previously determined dose to the right place.

7. In D3, a treatment plan is determined, where the treatment plan is defined in paragraph [0003] as:

A treatment plan including the appropriate selection of the beam locations, beam divergence angles, multileaved collimator settings, and so forth, controls the delivered radiation precisely to irradiate the cancerous region.

8. Hence, the treatment plan includes the beam parameters for achieving a certain dose at the cancerous region. The initially determined treatment plan parameters are updated based on changes detected in the treatment image ([0008], [0010], [0019]). This updating operation necessarily includes "dose calculation" in the above understanding, even if D3 does not use the expression. The opposed patent supports the same understanding of "dose calculation", as it also uses this expression to designate the calculation that is performed in order to update the treatment plan (and "aim the radiation beams correctly"), taking into account the changes identified in the treatment image (see paragraphs [0003], [0004], and [0016], and Figure 2, of the patent).

9. Hence D3 discloses dose calculation.

10. The contours memory in D3 stores anatomical (geometrical) data and also material property information "such as radiation attenuation or tissue density information" derived from the planning image ([0018]). These data are used to determine and optimize the initial treatment plan parameters ([0019], [0029]). This determination involves a dose calculation.

11. The contours are updated based on the deformations between the treatment image and the planning image ([0025], [0026], [0031]), where the deformations "account for changes in position, orientation, size, shape, and radiosensitivity of the tissue or organ" ([0027]). This means that information on radiosensitivity, a material property, must have been determined from the treatment image and used in the updating calculation. Moreover, paragraph [0034], referring to the updating of the contours stored in the contours memory, states:

If, however, the second imaging system 60 is a computed tomography scanner or other imager that does provide tissue density information, it can be included in the updating operation 122.

This teaching is clear and unambiguous in disclosing that tissue density information is, in some embodiments, used to update the contours in addition to geometrical information. The updated contours are subsequently used to calculate updated treatment plan parameters ([0026], [0032]) in a further dose calculation.

12. It follows that material property information such as radiosensitivity or tissue density information is used in the dose calculation involved in the update of the treatment plan.
13. The embodiments disclosed in paragraphs [0035] - [0038] also show that the opponent's understanding of the contour update in D3 being limited to geometrical contours is too narrow. Here, functional or biological information contained in treatment images is used to

update "biological or functional feature contours" in addition to merely updating the "anatomical feature contours", and to correct the treatment plan accordingly.

14. Hence, D3 also discloses embodiments, in which the same dose calculation is performed as defined in step e. of claim 1 of the patent in suit. The dose calculation in D3 is based on:

(a) A first basis for calculation, consisting of changes to the anatomical (geometrical) contours. These contours have been generated, initially, from the planning image and comprise, therefore, location and material property information from the planning image. During the update, location information from the fraction image is added.

(b) A second basis for calculation, consisting of changes to functional (non-geometrical) contours, like radiosensitivity or tissue density information. These contours have been generated, initially, from the planning image and are updated using material property information from the treatment image. To assign the material property information to the right locations, location information from the treatment image must necessarily be used as well.

15. In view of the above, the subject-matter of claim 1 is not novel over D3 (Articles 52(1) and 54(1), (2) EPC).

16. Therefore, the main request is not allowable.

First auxiliary request - occasion for filing and admission

17. The opponent asserted that the amendments to claim 1 in this request, compared to an earlier version of it, were mere clarifications. This was particularly true of the first and second of the three partial amendments. Clarity, though, was not a ground for opposition. Therefore, the amendments were not occasioned by a ground for opposition under Article 100 EPC and, consequently, did not comply with the requirement of Rule 80 EPC. For that reason, the first auxiliary request should not be admitted into the proceedings.
18. This argument is not persuasive. Compared with the patent, features have been added to claim 1 that restrict its scope of protection. In particular, claim 1 has been amended in three places that all refer to the particularities of dose calculation. The entirety of the three partial amendments addresses the question of patentability, which is a ground of opposition under Article 100(a) EPC.
19. Whether the amendments actually overcome the respective objection is irrelevant for the considerations on Rule 80 EPC (Case Law of the Boards of Appeal, 10th edition, IV.C.5.1.2(a), 4th paragraph). It is also irrelevant that the proprietor, in their attempt to establish novelty by properly defining what was, unsuccessfully, already intended to be defined in the previous version of the first auxiliary request (see first paragraph on page 3 of the opponent's submission of 16 January 2019), described the amendments with respect to the previous version as "clarifications".
20. Therefore, the first auxiliary request complies with Rule 80 EPC.

21. As a consequence, the opponent's argument against admission of the first auxiliary request has no basis.
22. In addition, it is noted that the first auxiliary request was first filed in response to the summons to oral proceedings before the Opposition Division, within the time limit set in accordance with Rule 116(1) EPC. The request was maintained during the opposition proceedings (points 1.3 and 7 of the minutes of oral proceedings before the Opposition Division: the proprietor confirmed and never withdrew the request) and re-filed with the proprietor's written reply to the opponent's appeal, together with reasons why the appealed decision should be upheld.
23. Hence, the first auxiliary request is taken into account (Article 12(4) RPBA 2007, which applies in this case according to Article 25(2) RPBA 2020).

First auxiliary request - novelty

24. Claim 1 was amended in steps c., d., and e.
25. The amendments in steps c. and d. are disclosed by D3, in particular by paragraph [0025] ("Preferably, the planning images are deformed to register with the treatment images..."), and by paragraphs [0027] and [0034] (see above points 11. and 14.(b)). The proprietor did not dispute that.
26. The amendment in step e. reads:

..., wherein the dose calculation is performed using material property information from the first basis for calculation in at

least a first region of the portion of the body and material property information from the second basis for calculation in at least a second region of the portion of the body, which is different from the first region.

27. This can be understood in two ways, as
- (a) using only material property information from the planning image in at least a first region, and using only material property information from the fraction image in at least a second region; or
 - (b) using at least material property information from the planning image in at least a first region, and using at least material property information from the fraction image in at least a second region.
28. The proprietor argued in favour of the narrower understanding (a), as being the only meaningful one. This understanding reflected the core of the invention as described in paragraphs [0010], [0011] and [0013] of the patent. Namely, using only material property information from the fraction image in certain regions, while using only the information from the planning image in other regions. This resulted in a composite image as described in paragraph [0029]. D3, in contrast, did not distinguish between different regions in its consideration of the treatment images. Hence, amended step e. introduced novelty over D3.
29. Contrary to the proprietor's view, (a) is not the only meaningful understanding of step e. Regardless of whether it might indeed have been intended by the proprietor, it is the wording of the claim and not the intension that defines the scope of the claim. The

broader understanding, (b), is entirely plausible. It includes the case that each information is used in each region.

30. The understanding (b) is not only plausible in view of claim 1 alone, but is also in agreement with the disclosure of the patent, which states, in paragraph [0013]:

Therefore, according to the invention, material property information may be taken from both the fraction image and the planning image, or from information related to each of these images, instead of relying only on the planning image for material property information. Preferably, different regions of the images are defined and it is determined that some regions should use material property information from the planning image and others should use material property information from the fraction image.

31. Thus, while understanding (a) reflects a particular embodiment of the invention, the broader understanding (b) reflects the general idea of the invention, which is to use material property information from the planning and the fraction images in the entire image, including each of its regions.
32. Since a claim must be accorded its broadest meaningful interpretation, understanding (b) must be applied in preference to (a).
33. The embodiments of D3 that use material property information, which were referred to in the context of

the main request, do not distinguish between regions. This implies that the radiosensitivity or tissue density information from the treatment image is used to update the contours, which were initially determined from the planning image, in the entire image. Therefore, the dose calculation uses the first and second bases for calculation (cf. point 14., above) in every region of the image.

34. For these reasons, the amendment fails to distinguish the subject-matter of claim 1 from D3.

35. The first auxiliary request is, therefore, not allowable for lack of novelty (Articles 52(1) and 54(1), (2) EPC).

Order

For these reasons it is decided that:

36. The decision under appeal is set aside.
37. The patent is revoked.

The Registrar:

The Chair:



D. Meyfarth

P. Scriven

Decision electronically authenticated