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Datasheet for the decision of 6 June 2023

Case Number: T 0976/20 - 3.4.01

Application Number: 14876485.5

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Language of the proceedings: EN

Title of invention:
METHODS AND SYSTEMS FOR BEAM INTENSITY-MODULATION TO FACILITATE RAPID RADIATION THERAPIES

Applicant:
The Board of Trustees of the Leland Stanford Junior University

Headword:
Rapid Radiation Therapies

Relevant legal provisions:
EPC Art. 84
RPBA 2020 Art. 12(4)

Keyword:
Clarity - main request (no)
Suitability of amendment for addressing the issues - all auxiliary requests (no)

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Case Number: T 0976/20 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 6 June 2023

Appellant: (Applicant)	The Board of Trustees of the Leland Stanford Junior University Office of the General Counsel Building 170, Third Floor, Main Quad P.O. Box 20386 Stanford, CA 94305-2038 (US)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 22 October 2019 refusing European patent application No. 14876485.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	P. Scriven
Members:	A. Medeiros Gaspar
	R. Winkelhofer

Summary of Facts and Submissions

I. The applicant appealed the Examining Division's decision to refuse the application and requested that the decision be set aside and a patent be granted on the basis of the main request on which the decision is based; or on the basis of one of auxiliary requests 1, 2A, 2B, 2C, 3A, 3B, 3C, 4A, 4B, 4C, 5A, 5B, 5C, 6A, 6B, 6C, 7A, 7B, and 7C, all submitted with the statement of grounds of appeal. Oral proceedings were also conditionally requested.

II. The Examining Division found claim 1 of the main request not to comply with Article 84 EPC and held it to lack novelty, having regard to the disclosure of document D2 (WO2005/115544 A1).

III. In a communication sent with a summons to oral proceedings, under Article 15(1) RPBA 2020, the Board expressed its preliminary opinion that, inter alia, claim 1 of the main request was not clear (paragraphs 1 to 16 of the communication) and that it did not appear to be patentable in view of D2 (paragraphs 17 to 21). The Board also indicated its inclination to not admit any of the auxiliary requests (paragraphs 22 to 30).

IV. One month ahead of the oral proceedings, the appellant submitted arguments in defense of the allowability of the requests on file. Document D3 (*Overview of light-ion beam therapy*, W. T.

Chu, ICRU-IAEA meeting 18-20 March, Columbus-Ohio)was also submitted as supporting evidence.

V. A few days ahead of the oral proceedings, the appellant announced that they would not attend.

VI. The oral proceedings were cancelled.

VII. Claim 1 of the main request reads:

A photon collimation assembly comprising:
one or more photon generating layer; and
a substantially planar collimator block having an upstream side towards an electron source when included in a treatment system for treating a targeted tissue and downstream side towards the targeted tissue, the upstream side being disposed adjacent the photon generating layer,
wherein the collimator block includes a plurality of channels, each extending from an inlet opening at the upstream side to an outlet opening at the downstream side of the collimator block,
wherein the channels and outlet openings and a thickness of the block are dimensioned so that a penumbra of individual beams transmitted through the channels is sufficiently sharp to provide sufficient resolution to maintain an intensity-modulation pattern of the beams when transmitted through the channels.

VIII. Claim 1 of the first auxiliary request reads (modifications with regard to the main request underlined or struck through):

A photon collimation assembly for use in a treatment system for treating a targeted tissue including an electron source configured to produce a two dimensional intensity-modulated pattern of electron beams, the photon collimation assembly comprising:
one or more photon generating layers comprising an array of photon production targets configured to generate a transverse distribution of photons in response to electron beam pulses rastered on the generating layers from the electron source; and
a substantially planar collimator block having an upstream side towards an electron source when included in a said treatment system ~~for treating a targeted tissue~~ and a downstream side towards the targeted tissue, the upstream side being disposed adjacent the photon generating layer,
wherein the collimator block includes a plurality of channels, each extending from an inlet opening at the upstream side to an outlet opening at the downstream side of the collimator block,
wherein the channels and outlet openings and a thickness of the block are dimensioned so that a penumbra of individual photon beams transmitted through the channels is sufficiently sharp to provide sufficient resolution at the

targeted tissue to maintain ~~an~~ the intensity-modulated~~ion~~ pattern ~~of the beams when transmitted through the channels~~.

IX. Claim 1 of auxiliary request 2A differs from claim 1 of auxiliary request 1, in that its final lines read (differences underlined):

... is sufficiently sharp to provide sufficient resolution at the targeted tissue to maintain a resolution of the intensity-modulated pattern within 1/10 of a width of the overall intensity-modulated pattern at the target tissue or smaller.

X. Claim 1 of auxiliary request 2B differs from claim 1 of auxiliary request 1, in that its final lines read (differences underlined or struck through):

... is sufficiently sharp to provide ~~sufficient~~ a resolution of the intensity-modulated pattern at the targeted tissue within 1/10 of a width of the overall intensity-modulated pattern at the target tissue or smaller.

XI. Claim 1 of auxiliary request 2C differs from claim 1 of auxiliary request 1, in that its final lines read (differences underlined or struck through):

...
is sufficiently sharp to provide ~~sufficient resolution~~ a projected width at the targeted tissue ~~to maintain the intensity-modulated pattern~~ within 1/10 of a width of the overall intensity-modulated pattern at the target tissue or smaller.

XII. Claim 1 of auxiliary requests 3A, 3B, and 3C is based on claim 1 of auxiliary requests 2A, 2B, and 2C, respectively, with several modifications introduced (as indicated underlined or struck through):

A photon collimation assembly for use in a treatment system for treating a targeted tissue ~~including~~, wherein the treatment system includes: (i) an electron source configured to produce a two dimensional intensity-modulated pattern of electron beams, and (ii) a patient support, the photon collimation assembly comprising
one or more photon generating layers ...
a substantially planar collimator block having an upstream side towards an electron source when included in a said treatment system and a downstream side towards the targeted tissue of said patient on a said patient support, the upstream side ...
wherein the collimator block includes...
wherein the channels and outlet openings and a thickness of the block are dimensioned so that, when transmitted through the photon collimation assembly

to said targeted tissue located on said patient support, a penumbra ... tissue or smaller.

XIII. Claim 1 of auxiliary requests 4A, 4B, and 4C adds a further limitation at the end of claim 1 of auxiliary requests 3A, 3B, and 3C, respectively, so that the final lines read (addition underlined):

...
tissue or smaller and to provide a spatial positioning accuracy of within 3mm and intensity within 3% of the desired dose pattern in the treatment plan.

XIV. Claim 1 of auxiliary requests 5A, 5B, and 5C modifies the preamble of claim 1 of auxiliary requests 4A, 4B, and 4C, respectively, so that it reads (modifications underlined or struck through):

A treatment system comprising:
a patient support;
an electron source configured to produce a two-dimensional intensity-modulated pattern of electron beams selected based on a treatment plan defining a desired dose pattern for a targeted tissue of a patient; and
a photon collimation assembly ~~for use in a treatment system for treating a targeted tissue including an electron source configured to produce a two-dimensional~~

~~intensity-modulated pattern of electron beams, the photon collimation assembly~~ comprising:
one or more photon generating layers ...

XV. Claim 1 of auxiliary requests 6A, 6B, and 6C adds to claim 1 of auxiliary requests 5A, 5B, and 5C, respectively, a limitation to the feature defining the electron source, so that it reads (addition underlined):

...
an electron source configured to produce a two-dimensional intensity-modulated pattern of electron beams selected based on a treatment plan defining a desired dose pattern for a target tissue of a patient, <u>wherein the electron beams are high energy electron beams having an energy between 50 MeV and 250MeV;</u> and
...

XVI. Claim 1 of auxiliary requests 7A, 7B, and 7C adds a feature at the end of claim 1 of auxiliary requests 6A, 6B, and 6C, respectively, so that the final lines read (addition underlined):

...
defined in the treatment plan; <u>and an active cooling feature</u>.

Reasons for the Decision

Decision in written procedure

1. The appellant's announcement that they would not attend the oral proceedings is equivalent to a withdrawal of their request for oral proceedings (Case Law of the Boards of Appeal, 10th ed., III. C.4.3.2).

2. Consequently, this decision is issued on the basis of the appellant's written submissions.

Context of the invention

3. The invention relates to radiation therapy (application: paragraph [0003]).

4. It is concerned with the accurate delivery of an intensity-modulated radiation pattern to target tissue of a patient.

5. A photon collimation assembly is a key element of a treatment system for intensity-modulated radiation therapy (IMRT). It's internal structure and placement with regards to the other elements of the treatment system ensures that the therapeutic photons are generated and directed towards the target as intended.

Main Request - clarity

6. Claim 1 of the main request defines a collimation assembly comprising one or more photon generating layers, and a collimator block including a plurality of

channels each extending from an inlet opening on the upstream side of the collimator block to an outlet opening on the downstream side of the collimator block.

7. The claim also defines that *the channels and the outlet openings and thickness of the collimation block are dimensioned so that a penumbra of individual beams transmitted through the channels is sufficiently sharp to provide sufficient resolution to maintain an intensity-modulation pattern of the beams when transmitted through the channels.*

8. The Examining Division identified several clarity issues with the result to be achieved in this definition.

9. The appellant argued that a definition in terms of a result to be achieved was appropriate in the present case, and that the claim made clear that it was the thickness of the block (i.e. the length of the channels), as well as the channels and outlet openings that needed to be dimensioned so as to achieve the result.

10. However, even if the tuning of such parameters were seen as not imposing an undue burden on the skilled person, the result to be achieved is still not clearly defined, with the consequence that the skilled person would not know when the parameters fall within the definition.

11. Firstly, it is not clear what is to be understood by the stated aim of maintaining *an intensity-modulation pattern,* which appears to conflict with the reference to a *penumbra of the individual beams transmitted through the channels*. The use of vague expressions such

as *sufficiently sharp* or *sufficient resolution* further obscures what is meant by "maintenance".

12. The appellant argued that, taking into account the whole disclosure as filed, and in particular the disclosure of figure 13, the skilled person would understand what was meant by the expression *maintain the intensity-modulation pattern*.

13. These arguments fail, however, simply because the claims need to be clear in themselves.

14. In any case, the description of the application also fails to provide any clarification as to what should be understood by *sufficiently sharp* or *sufficient resolution* or under *maintenance of a pattern*. There is no objective measure of sufficiency (of sharpness or of resolution, if there is a difference), and figure 13 does not explain what is meant by the maintenance of a pattern.

15. Document D3, submitted in reaction to the preliminary opinion of the Board, while suggesting that the terms *penumbra*, *sharpness*, and *resolution* were indeed employed in the art, when referring to the effects of collimation, does not suggest that a precise definition existed for what is to be understood under "maintenance" of the intensity-modulation pattern, or sufficiently sharp penumbra, or a sufficient resolution.

16. Furthermore, whether or not a certain intensity-modulation pattern is "maintained", when transmitted through the collimator block, depends not only on the dimensions of the collimator block and of its channels, but also on the intensity-modulated pattern generated

by the photon generating layer. The pattern is not defined in the claim.

17. The claim also does not define where the intensity-modulated pattern is to be "maintained", whether immediately at the output of the collimator block or at the target tissue.

18. The appellant argues that the intensity-modulation pattern in the definition of the result to be achieved would be understood as the intensity modulation at the target tissue, as this was the only technically sensible interpretation.

19. However, not only is this interpretation not made clear by the claim wording alone, but it also, if followed, raises a further clarity issue. In fact, the intensity-modulation pattern produced at the target tissue depends not only on the collimation assembly, but also on its placement and orientation with regards to the target tissue, as well as on the shape of the target tissue.

20. Hence, not only is the result to be achieved not clearly defined in the claim, but it also cannot be uniquely determined exclusively on the basis of features of the collimation arrangement the claim seeks to define.

21. The appellant further stated that the skilled person would be aware that a collimator will need be designed to function with a target tissue at a certain (i.e. optimal) distance away, e.g. in a way similar to focal length of a lens and that the skilled person would also know what the high precision radiation treatment for that target tissue would be. These are not parameters

that would not be known or with which the skilled person would not be concerned.

22. These statements, rather than defending the appellant's case, confirm the dependency of the result defined in the claim on all those further parameters, which are neither intrinsic to the collimation assembly nor further defined in the claim.

23. In summary, the claim formulation does not clearly define the collimator assembly for which protection is sought. In fact, whether or not the result defined in the claim is achieved depends not only on the collimation assembly, but also on the particular use of it, and on the user's particular understanding of whether a certain *intensity-modulation pattern* is maintained or not.

24. Therefore, claim 1 of the main request is not clear (Article 84 EPC) and, consequently, the main request is not allowable.

Auxiliary Requests

25. The auxiliary requests were filed with the statement of grounds of appeal.

26. They are amendments in the sense of Article 12(4) RPBA 2020, which may be considered only at the discretion of the Board.

27. Under Article 12(4) RPBA 2020, third sentence, the Board shall exercise its discretion in view of, inter alia, the complexity of the amendment, the suitability of the amendment for addressing the issues which led to

the decision under appeal, and the need for procedural economy.

28. In the present case, the amendments, rather than solving the clarity issues identified in the contested decision, introduce more.

29. For instance, the further definition of the photon collimation assembly as being *for use in a treatment system* does not suitably address the issue identified under reasons 6.1.2 of the decision (see paragraphs 19 and 20 above), since the claim is still directed to a collimation block defined by means of a result to be achieved that depends not only on the characteristics of the collimation assembly itself, but also on its relative position with regards to other elements of the treatment system in which the collimator is to be used, and which are not part of the subject-matter claimed.

30. Additionally, auxiliary requests 4A to 7C add, to claim 1, further results to be achieved, namely, *to provide a spatial positioning accuracy within 3mm and intensity within 3% of the desired dose pattern defined in the treatment plan*. Such a formulation, rather than clarifying what constitutes a "sufficiently sharp penumbra", introduces further clarity issues, not only because the further result to be achieved is defined by reference to an undefined treatment plan, which is not part of the system defined, but also because it is not clear which features of the collimation assembly, or of the system defined, bring about such results.

31. In conclusion, amendments introduced with the auxiliary requests are not suitable for addressing the clarity issues which lead to the decision under appeal (items 5

and 6.1 of the decision) and which, as reasoned above, render the main request unallowable.

32. Therefore, the auxiliary requests are not considered (Article 12(4) RPBA 2020).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

D. Meyfarth P. Scriven

Decision electronically authenticated