

**Internal distribution code:**

- (A) [ - ] Publication in OJ
- (B) [ - ] To Chairmen and Members
- (C) [ - ] To Chairmen
- (D) [ X ] No distribution

**Datasheet for the decision  
of 23 May 2022**

**Case Number:** T 1854/16 - 3.4.01

**Application Number:** 09769703.1

**Publication Number:** 2293844

**IPC:** A61N5/10, A61B19/00, G01R33/54,  
G01R33/56, A61N7/00, A61B6/03,  
A61B8/00, A61B8/13

**Language of the proceedings:** EN

**Title of invention:**  
SYSTEM FOR BRACHYTHERAPY

**Patent Proprietor:**  
Koninklijke Philips N.V.

**Opponent:**  
Nucletron Operations B.V.

**Headword:**  
System for Brachytherapy / Philips

**Relevant legal provisions:**  
EPC Art. 100(a), 56  
RPBA Art. 12(4)

**Keyword:**

Inventive step - main request (no) - auxiliary request I' (no)  
- auxiliary request I'' (yes)  
Late-filed document - admitted (no)



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

**Case Number: T 1854/16 - 3.4.01**

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.01**  
**of 23 May 2022**

**Appellant I:**  
(Patent Proprietor)

Koninklijke Philips N.V.  
High Tech Campus 52  
5656 AG Eindhoven (NL)

**Representative:**

Philips Intellectual Property & Standards  
High Tech Campus 52  
5656 AG Eindhoven (NL)

**Appellant II:**  
(Opponent)

Nucletron Operations B.V.  
Waardgelder 1  
3905 TH Veenendaal (NL)

**Representative:**

Roberts, Gwilym Vaughan  
Kilburn & Strode LLP  
Lacon London  
84 Theobalds Road  
London WC1X 8NL (GB)

**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
9 June 2016 concerning maintenance of the  
European Patent No. 2293844 in amended form.**

**Composition of the Board:**

**Chairman** P. Scriven  
**Members:** T. Zinke  
D. Rogers

## **Summary of Facts and Submissions**

- I. An opposition was filed against the entirety of the European Patent.
- II. In an interlocutory decision, the Opposition Division decided that, account being taken of the amendments made by the patent proprietor during the opposition proceedings according to auxiliary request I, the patent and the invention to which it related met the requirements of the EPC.
- III. Both the patent proprietor (appellant I) and the opponent (appellant II) appealed.
- IV. With its notice of appeal, the opponent requested that the decision be set aside and the patent revoked.
- V. With its statement setting out the grounds of appeal, the proprietor requested that the decision be set aside and that the opposition be dismissed. The proprietor also requested maintenance of the patent on the basis of one of auxiliary requests I to VI, as filed during opposition proceedings, with a submission of 23 March 2016. With a response to the opponent's statement of grounds, the patent proprietor also re-filed the claim sets for the auxiliary requests.

- VI. Further, the proprietor argued that none of the documents filed after the expiry of the opposition period should be considered in the appeal proceedings.
- VII. The Board arranged oral proceedings and issued its preliminary opinion, in accordance to Article 15(1) RPBA.
- VIII. With its response to the Board's preliminary opinion, the proprietor filed claim sets for further auxiliary requests I', I'', II', III', IV', V', VI' and relabeled auxiliary request I (the claim set the Opposition Division considered allowable) "auxiliary request I''".
- IX. The opponent did not file a substantive response to the Board's preliminary opinion, but indicated that it would not attend the oral proceedings.
- X. Oral proceedings took place on 23 May 2022. The opponent did not attend.
- XI. As confirmed by the proprietor at the start of oral proceedings, the order of the 14 requests was: the main request followed by auxiliary request I', I'', I''', II, II', III, III', IV, IV', V, V', VI, and VI'.
- XII. Claims 1 and 7 of the main request (patent as granted) read as follows:

1. A brachytherapy system (10) for a target region (200), the system comprising:

- an applicator (100) having a plurality of channels (110) that are hollow and expandable, the applicator being implantable in the target region;

- a tracking device (175) having a size and shape so as to be advancable and retractable through at least a portion of the plurality of channels, and adapted to receive a signal;

- a processor (550), being in communication with the tracking device,

wherein the system is arranged to receive from an imaging device (500) an image of the target region

characterized in that:

- the brachytherapy system further comprises a tracking signal generator (108) adapted to generate a signal receivable by the tracking device;

- the processor is adapted to determine:

- the movement of the tracking device on the basis of signal characteristics of the signal received by the tracking device,

- a position of one or more of the plurality of channels with respect to the target region based on a tracked movement of the tracking device, and the position of the one or more of the plurality of channels in the image based at least in part on the channel position determination from the tracking device.

7. A computer readable storage medium comprising a computer executable code to cause a computing device of the brachytherapy [sic] system (10) of claim 1 to execute the steps of:

determining a position of one or more of a plurality of hollow channels (110) of an applicator (100) of said system with respect to a target region (200) based at least in part on a tracked movement of a tracking device (175), the applicator being positionable in the target region, the tracking device being movable through the one or more of the plurality of channels, wherein movement of the tracking device is determined on the basis of signal characteristics of a signal emitted from a signal generator received by the tracking device, and generating at least a portion of a brachytherapy plan for administering a radiation dose based on the position of the one or more of the plurality of channels.

XIII. In auxiliary request I', claim 1 and its dependent claims remained.

XIV. In auxiliary request I'' (the form the Opposition Division found allowable), claim 1 is claim 2 of the patent. Claim 6 is an amended version of claim 7 of the patent. The amendments read:

1. ...

*wherein the brachytherapy system further comprises*

*- one or more fiducial markers (400) in communication with the tracking signal generator (180) and mountable on an external portion of the target region, wherein the processor (550) determines the location of the one or more of the plurality of channels in the image based in part on the position and orientation of the one or more fiducial markers.*

6. ...

*wherein the computer-readable storage medium further comprises computer-executable code for causing the computing device to*

*- localise the position of the one or more of the plurality of hollow channels (110) based in part on the position and orientation of one or more markers (400), which are in communication with the signal generator, connected to an external portion of the target region.*

XV. The other auxiliary requests are not relevant for this decision.



## **Reasons for the Decision**

*Main request (patent as granted)*

*Opposition grounds under Article 100(a) EPC in combination with Article 52(2)(c) EPC (mental acts as non-inventions) and with Article 53(c) EPC (exceptions of patentability for medical methods)*

1. In the disputed decision, the Opposition Division concluded that the opposition grounds under Article 100(a) EPC in combination with Articles 52(2)(c) and 53(c) EPC against the patent as granted were unfounded (decision, reasons, sections 15 and 16).
2. The opponent did not contest this part of the decision during appeal proceedings.
3. Hence, the Board has no power to consider this part of the decision under appeal.

*Opposition grounds under Article 100(c) EPC (unallowable amendment), Article 100(b) EPC (insufficient disclosures), Article 100(a) EPC in combination with Articles 52(1) and 54 EPC (lack of novelty)*

4. In the disputed decision, the Opposition Division concluded that the opposition grounds under Articles 100(c) EPC, 100(b) EPC, and 100(a) in combination with Articles 52(1) and 54 EPC (lack of novelty) against the patent as granted were unfounded (decision, reasons, sections 13, 14, 20 to 23).

5. With the statement of grounds, the opponent explicitly maintained the corresponding objections, but only provided a copy of its arguments in its notice of opposition or (with regard to late-filed document 012) in a submission of 4 February 2015 to the Opposition Division (Statement of grounds, Annex). No explanation was given as to why the decision of the Opposition Division in this regards was wrong.
6. Since - contrary to Rule 99(2) EPC - no reasons are provided for setting aside the findings of the Opposition Division with regard to these aspects, these opposition grounds are not admissibly raised in the appeal. The Board has no power to review the Opposition Division's findings on these points.

*Opposition ground under Article 100(a) EPC in combination with Article 56 EPC (lack of inventive step)*

7. In the decision under appeal, the Opposition Division held that the subject-matters of claims 1 and 7 of the patent lacked inventive step with regard to a combination of documents 01 (WO-A-2008/045 812) and 012 (US-A-2007/0078327).
8. With the statement of grounds, the proprietor requested that the Opposition Division's decision to admit late-filed document 012 into the opposition proceedings be set aside. The proprietor also argued that, irrespective of whether document 012 was considered, the subject-matters of the independent claim 1 and claim 7 involved an inventive step.

*Document 012*

9. The Opposition Division admitted document 012 into the opposition proceedings (decision, reasons, sections 17.1 and 18), despite its filing after expiry of the opposition period.
10. The Board should only overrule such a decision, if it concludes that the Opposition Division applied the wrong principles, took no account of the right principles, or exercised its discretion in an unreasonable way, thus exceeding the proper limits of its discretion.
11. The Board cannot identify any error in the principles applied by the Opposition Division, or anything unreasonable about it. On the contrary, the Opposition Division demonstrated the relevance it saw in 012, when considering it for the evaluation of inventive step of the proprietor's main request. In section 17.1 of the decision under appeal, the Opposition Division clearly stated that it considered document 012 to be *prima facie* relevant. Hence, the Opposition Division used the *prima facie* relevance criterion, which is a well-established criterion for admitting late-filed documents into the opposition proceedings.
12. Accordingly, the Board does not set aside the discretionary decision to admit 012, and will take account of this document.

*Inventive step*

13. The Board considers document 012 to represent the closest prior art amongst those adduced by the

opponent. The only feature of claim 1 of the main request that O12 does not disclose is that the hollow channels are expandable (as already identified by the Opposition Division, see decision, reasons, section 30).

14. The Board agrees with the definition of the objective technical problem of adapting the device disclosed in O12 for treatment of a cavity.
15. Document O1 discloses a device comprising hollow expandable channels for brachytherapy (figs 1A and B, 3 and 4, claim 1) and applicable for use in a natural body cavity or a lumpectomy void (page 1, lines 5 to 9; page 3, lines 8 to 11).
16. As O1 and O12 describe similar devices and the same medical field, the skilled person would be prompted to consider a combination of their teaching. This would lead to the provision of expandable channels.
17. The subject-matter of claim 1 is thus not inventive in the meaning of Article 56 EPC over the combination of documents O1 and O12.
18. The same argumentation applies, *mutatis mutandis*, to the subject-matter of claim 7.
19. With the statement of grounds, the proprietor argued that neither O1 nor O12 disclosed a "two-step" approach for determining the position of an expandable applicator channel in an image, as defined in the independent claims of the main request, i.e. that:

... firstly the position of the expandable applicator channel is determined with

*respect to a target region by performing signal-based tracking of a movement of a tracking device within the expandable applicator channel and wherein secondly the position of the expandable applicator channel with respect to the target region, which has been determined in this way, is used for determining the position of the expandable applicator channel in the image. ...*

(statement of grounds, bottom of page 2), and for that reason no combination of O1 and O12 would result in the claimed subject-matter.

20. However, as pointed out by the opponent (reply to patent proprietor's appeal, page 1, penultimate paragraph), neither claim 1 nor claim 7 of the patent explicitly defines a "two-step"-approach.
21. The proprietor also argued that, in document O12, there was no disclosure that the position of the channels in an image was determined (cf. for instance, section 1.3.1 of the proprietor's response to the Board's preliminary opinion).
22. Document O12 discloses two imaging means: first imaging means, for instance an ultrasound probe, that images the target region in order to generate a treatment plan (paragraph [0063]) and second imaging means for visualizing the proximal end of an inserted treatment channel in order to align it with a connecting element (paragraph [0064]). Whereas it is not explicitly disclosed that the first imaging means also takes an image of the inserted treatment channels, it is disclosed that the image taken by the first imaging

means is used for treatment planning and for determining a preplanned plurality of locations of a plurality of treatment channels used (paragraph [0053]). Since these pre-planned locations of the treatment channels can only refer to the image of the target region, it is implicit that also these preplanned locations of the treatment channels are determined in the image. In document 012, the tracking device is then used to identify at least one of the plurality of hollow needles as a treatment channel (paragraph [0060]), such identification thus automatically determining the location of the particular identified treatment channel in the image. Hence, document 012 discloses implicitly determining the position of channels in the image.

23. Hence, the main request is not allowable.

*Auxiliary request I'*

24. Since claim 1 of auxiliary request I' is identical to claim 1 of the main request, the lack of inventive step objection discussed above applies equally.

25. Auxiliary request I' is not allowable.

*Auxiliary request I'' (the claim set the Opposition Division found allowable)*

26. Starting from document 012, claim 1 of auxiliary request I'' defines two distinguishing features:  
(i) the hollow channels are expandable and  
(ii) the brachytherapy system further comprises one or more fiducial markers

(400) in communication with the tracking signal generator (180) and mountable on an external portion of the target region, wherein the processor (550) determines the location of the one or more of the plurality of channels in the image based in part on the position and orientation of the one or more fiducial markers.

27. These features solve two problems separately, i.e.
- (i) to adapt the device for a treatment of a cavity and
  - (ii) to facilitate the determination of channel positions with regard to the target region.
28. As already indicated by the Opposition Division (see decision, reasons, section 34.3.4), however, distinguishing features (i) and (ii) together also solve a third problem (synergistic effect), i.e.
- (iii) to improve localisation of implanted movable (due to their expandability) channels.

*Documents 03, 06, 07*

29. In the decision under appeal, the Opposition Division discussed the inventive step of this claim set by analysing the teachings of documents 03 (Seiler, Blattmann et al. "A novel tracking technique for the continuous precise measurement of tumour positions in conformal radiotherapy", Physics in Medicine and Biology, (September 2000), pp N103 - N110); 06 (Wood, Hui Zhang et al. "Navigation with Electromagnetic Tracking for Interventional Radiology Procedures: A

Feasibility Study", Journal of Vascular and Interventional Radiology, vol. 16, no. 4, (April 2005), pages 493-505) and O7 (Kruecker, Sheng Xu et al. "Electromagnetic Tracking for Thermal Ablation and Biopsy Guidance: Clinical Evaluation of Spatial Accuracy", Journal of Vascular and Interventional Radiology, vol. 18, no. 9, (September 2007), pages 1141-1150).

30. The Opposition Division held that these documents disclosed external fiducials as such, but that none of them would have prompted the skilled person to combine their teachings with that of document O12 to arrive at the claimed subject-matter (decision, reasons, section 34.4).
31. The Board agrees with the Opposition Division. In particular, none of these documents deal with brachytherapy, none of them deals with expandable channels, and none of them deals with the relative localization between moving treatment channels and moving target regions. Hence, none of them provides a hint, for a skilled person, at combining their teachings with document O12 to address problem (iii).
32. With its statement of grounds, the opponent argued that the Opposition Division erred in its analysis of these documents (pages 4 to 5, first three paragraphs under the sub-headline: "Fiducial markers in communication with tracking signal generator"). The opponent argued that these three documents dealt with using external markers in order to register medical images, which was the same purpose as the use of the fiducial markers in claim 1 of auxiliary request I'.



33. However, the opponent's analysis does not take into account that, with the tracked fiducials, which are mountable on an external portion of the target region, the image is not only registered with the electromagnetic tracking data at the start of the treatment. In addition, relative movement of the target region to the applicator can be taken into account due to continuous tracking of the fiducials. For instance, as it is discussed in paragraph [0033] of the patent, if the applicator is not in the original position at which the therapy was planned, a transform can be determined by the processor between the current and original location of the applicator relative to the fiducials ("markers 400") and the target region ("targeted anatomy 200"). This transform can be used by the processor to operate on the planning image, such as from a planning image memory, to shift the relative location of the applicator and the target region in accordance with the transform to form a transformed therapy planning image. This shifted information can be used by the processor to generate a new brachytherapy plan.
34. Document 03 only discusses movement of a sensor somehow attached to a tumour (section 4.1) in a fixed coordinate system, with no relation to target regions. In document 06 the fiducials are passive and their position is determined by manually touching them with an electromagnetic sensor (page 495, first complete paragraph), which is time consuming. Document 07 (Abstract, "Materials and Methods") discloses active fiducials for image registration, but does not disclose that the fiducials should be mounted to target regions, so that a relative movement between target regions and a further electromagnetic tracking sensor could be

determined. It mentions "patient motion" as a source of error (Abstract, "Results").

35. Hence, since none of documents O3, O6, and O7 discloses the combined use of an electromagnetic tracking sensor together with tracked fiducials mountable on target regions, the skilled person would not get a hint at applying their teachings to solve at least technical problem iii) above.

*Late-filed documents O5c, O19, O20a, O20b, O20c*

36. With its statement of grounds, the opponent filed additional documents O5C (Aurora User Manual), O19 (US 2002/0193685), O20a ("Evaluation and Extension of a Navigation System for Bronchoscopy Inside Human Lungs", 2007), O20b (SPIE Digital Library Volume 6509, Medical Imaging 2007: Visualization and Image-Guided Procedures), O20c (WO-A-2005/084571). Document O5C was referred to as "O5b" in the statement of grounds, but the Board relabeled it O5C, since a different document had already been filed with the label O5B (the opponent's submission of 24 March 2016 in proceedings before the Opposition Division).
37. The opponent used these additional documents to argue a lack of inventive step for the claim set found allowable by the Opposition Division, i.e. current auxiliary request I'. In particular, these documents were cited against the amended feature introduced into the independent claims of auxiliary request I' defining the fiducial markers (cf. opponent's statement of grounds, page 5, first to fifth complete paragraphs). The opponent explained the late submission of these documents as a response to the proprietor's

submission of this request with their letter of 23 March 2016 in response to the Summons to attend Oral Proceedings before the Opposition Division. Allegedly these documents had come to light at this stage in a search for additional material (opponent's statement of grounds, page 3, first paragraph).

38. According to Article 12(4) RPBA 2007 - which applies under Article 25(2) RPBA 2020 - it is in the Board's power to hold inadmissible facts, evidence, or requests which could have been presented in the first instance proceedings.
39. Since the subject-matter of independent claim 1 of auxiliary request I' is identical to that of claim 2 of the patent, this subject-matter was relevant from the beginning of the opposition proceedings. Hence, documents against this combination should have been filed already during the opposition period. At the very latest prior to oral proceedings before the Opposition Division - when the proprietor filed this request one month in advance of the oral proceedings - should the opponent have filed any additional prior art, the admission of which would then have been at the discretion of the Opposition Division.
40. The time of submission of these additional documents is an indication that they should not be admitted, but their relevance is also not prima facie evident. Whereas all of them deal with fiducial markers in addition to tracking devices, this does not automatically make them relevant. 012 does not deal at all with moving treatment channels or moving target regions. The teaching of 012 relies on fixed positions of the treatment channels relative to the target regions, and the aim of 012 is to select the correct

(fixed) treatment channel of a plurality of (fixed) treatment channels. Movement of a particular treatment channel with regard to the target region is not foreseen in O12. Hence, there is no motivation for the skilled person to use the fiducial markers of these additional prior art documents in combination with O12.

41. Hence, these additional documents O5C, O19, O20a, O20b, and O20c are not admitted into the appeal proceedings (Article 12(4) RPBA 2007).

*Inventive step analysed starting from document O1 as closest prior art*

42. In its statement of grounds (page 6, penultimate paragraph), the opponent argues against inventive step on the basis of O1 as the skilled person's starting point.
43. Basically, the opponent's discussion of lack of inventive step starting from document O1 repeats the argumentation as provided when evaluating inventive step starting from document O12, namely that the additional feature in auxiliary request I'' as compared to the main request is nothing more than common general knowledge.
44. As explained in detail above, the Board is not persuaded by this argumentation, but sees, in the claimed subject-matter, a non-obvious solution to technical problem (iii) that is not addressed by any of the prior art documents on file.

### *Conclusion*

45. Since the claim set considered allowable by the Opposition Division is also considered allowable by the Board, the decision of the Opposition Division is upheld. Consequently, the appeals by the proprietor (appellant I) and by the opponent (appellant II) are dismissed.

### **Order**

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

The appeals of appellants I and II are dismissed.

The Registrar:

The Chair:



C. Eickhoff

P. Scriven

Decision electronically authenticated