

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2017/054680

International filing date (day/month/year)
01.03.2017

Priority date (day/month/year)
09.03.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61N5/10

Applicant
KONINKLIJKE PHILIPS N.V.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of this opinion

see form PCT/ISA/210

Authorized Officer

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

the entire international application

claims Nos. 11-21

because:

the said international application, or the said claims Nos. 11-21 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for the whole application or for said claims Nos. 11-21

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13^{ter}.1(a) or (b).

See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>2-7</u>
	No: Claims	<u>1, 8-10</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-10</u>
Industrial applicability (IA)	Yes: Claims	<u>1-10</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

1 **Re Item III**

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1.1 No opinion under Article 33(1) PCT will be established for the subject-matter of claims 11-21 since no Search Report has been established (Article 17(2)(a)(ii) and (b) and Rule 39.1(i)(v)(vi) PCT) for these claims (Rules 66.1(e) and 70.2(d) PCT).
- 1.2 Claims 11-21 relate to a subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(i)(v)(ii) PCT, namely to a planning method consisting of the computer-implemented performance of a mathematical algorithm and the mere presentation of the results without defining any interaction with elements outside the computer which could bring a further technical effect going beyond the "normal" physical interactions between the program and the computer on which it is run (cf.: PCT-EPO/GL G-II, 3.3, 3.6, 3.7 and General Part, 3.2 Anx II; EPG 20, 220, Anx IV ; PCT/GL/ISPE 9.05, 9.15, A9.15, A9.15[2], and 9.11-9.14). Consequently, no opinion under Article 33(1) PCT will be formulated with respect to the subject-matter of these claims (Article 34(4)(a)(i) and (b) and Rule 67.1(i)(v)(vi) PCT).

2 **Re Item V**

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1 US 2015/087879 A1 (NELMS BENJAMIN E [US]) 26 March 2015 (2015-03-26)
- D2 US 2016/030767 A1 (KUMAR PRASHANT [IN] ET AL) 4 February 2016 (2016-02-04)
- D3 US 2014/350322 A1 (SCHULTE REINHARD W [US] ET AL) 27 November 2014 (2014-11-27)
- D4 US 2007/201614 A1 (GOLDMAN SAMUEL P [CA] ET AL) 30 August 2007 (2007-08-30)

D5 US 2011/085643 A1 (ZHU LEI [US] ET AL) 14 April 2011
(2011-04-14)

2.1 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

D1 discloses:

A radiation therapy planning device (26) comprising:
a computer including a display device (42); and
at least one non-transitory storage medium (46,28) storing instructions readable and executable by the computer to perform operations including:
computing an achievability estimate (§70,§71,§72,§74; Report 100; 102-108, 112-126; Figs. 5 and 7) for an intensity modulated radiation therapy (IMRT) geometry (36, §6) including a target volume to be irradiated, an organ at risk, and at least one radiation beam based on relative spatial arrangement of the target region, the OAR, and the at least one radiation beam; and
displaying (§72), on the display device, the achievability estimate or information generated based on the achievability estimate.

2.2 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

D2 discloses:

A radiation therapy planning device comprising:
a computer (Fig. 1) including a display device (10); and
at least one non-transitory storage medium storing instructions readable and executable by the computer to perform operations including:
computing an achievability estimate (§9,§26,§33-§37) for an intensity modulated radiation therapy (IMRT) geometry (Fig. 2) including a target volume to be irradiated, an organ at risk (OAR), and at least one radiation beam based on relative spatial arrangement of the target region, the OAR, and the at least one radiation beam; and
displaying (46; §27, §38,§39,§42), on the display device, the achievability estimate or information generated based on the achievability estimate.

2.3 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

D3 discloses:

A radiation therapy planning device comprising:
a computer (Figs. 1A,1B) including a display device (§65); and
at least one non-transitory storage medium storing instructions readable and executable by the computer to perform operations including:
computing an achievability estimate (§18,§23,§82,§98-§100) for an intensity modulated radiation therapy (IMRT) geometry (401-430; 800, 1300,1400) including a target volume to be irradiated, an organ at risk (OAR), and at least one radiation beam based on relative spatial arrangement of the target region, the OAR, and the at least one radiation beam; and
displaying (§65), on the display device, the achievability estimate or information generated (namely the treatment plan) based on the achievability estimate (§18,§23,§82,§98-§100).

- 2.4 Dependent claims 2-10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), since they all relate to particular constructional implementations of the treatment planning device of D1 which are either known from the documents cited in the International Search Report (cf. the passages mentioned therein) or would come within the scope of the customary practice followed by persons skilled in the art, especially since they do not appear to provide any special or unexpected technical effect or any solution to a particular problem. See, in particular, following passages regarding claims (Re.claim#):

Re.2-7: The relationship between the achievability of a plan and the number of beamlets passing through the OAR is well known in the art, see §43,§79,§80,§101,§147 and §148 in D4 or §4,§32, Table § and §80-§81 in D5.

Re.8: The consideration of the relative spatial arrangement of the target and the OAR, the MLC configuration and the weighted objection functions suggested in these claims do not appear to provide any special or unexpected technical effect.

3 **Re Item VII**

Certain defects in the international application

- 3.1 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 3.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D5 is not mentioned in the description, nor are these documents identified therein.