PATENT COOPERATION TREATY

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INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

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.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2018/075903	25.09.2018	26.09.2017

International Patent Classification (IPC) or both national classification and IPC
INV. G16H50/20 G16H20/10

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 43*bis*.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 notifed the International Bureau under Rule 66.1*bis*(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:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Bankwitz, Robert Telephone No. +49 89 2399-0

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2018/075903

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 43*bis*.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 13*ter*.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 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.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. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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 document:

D1 US 2017/095670 A1 (GHAFFARI ROOZBEH [US] ET AL) 6 April 2017 (2017-04-06)

1 **Inventive Step**

1.1 The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claims 1 - 20 is not inventive within the meaning of Article 33(3) PCT.

1.2 Having regard to claim 1, document D1 is regarded as the closest prior art. It discloses:

1.3 **Assessment of inventive step of mixed-type inventions**

1.3.1 Claim 1 comprises technical and non-technical features. The assessment of inventive step is therefore carried out in accordance with section G-VII, 5.4 of the Guidelines for Examination.

1.3.2 In the case of claims comprising technical and non-technical features, only those features which contribute to the technical character of the invention are taken into account for the assessment of inventive step.

1.3.3 **Closest prior art and distinguishing features**

1.3.4 D1 is considered to be a suitable starting point for the assessment of inventive step of claim 1 and is taken as the closest prior art.

1.3.5 D1 discloses:

A clinical therapy system, comprising:
a drug delivery device configured to delivery medication to a patient;
one or more therapy devices configured to provide therapy or to monitor the patient;
a computer programmed to perform a CDS method including:
(*par. 9, device devices providing drug delivery and electrical stimulation (therapy) - see also par. 33; regarding the computer, see par. 43-45 and Fig. 1, external hub (ref. 130) and analytics (ref. 140)*)

receiving clinical context data for the patient from ~~a health information system (HIS)~~ [a remote source] (*par. 12-13, e.g. the temperature is context data which is clinical since it pertains to the context of medical therapy*);

receiving high fidelity data comprising real time measurements for the patient from one or more of the drug delivery device, one or more vital sign sensors, and at least one device of the one or more therapy devices (*par. 10-11, "sensed condition information" implies receiving measurements from the sensing devices (=vital sign sensors); real time measurements are implied due to the requirements of controlling treatment of therapy*);

generating a ~~clinical prediction~~ [therapy recommendation] for the patient based on a combination of the clinical context data and the high fidelity data (*par. 12, determining an algorithm for controlling the operation of a device, e.g. a mild condition neurostimulation algorithm - i.e. the determining is a therapy recommendation; see also 38, 46, 95-98, 112*);

outputting a therapy recommendation for the patient ~~based on the clinical prediction for the patient~~; (*outputting the therapy recommendation is necessarily implied when controlling operation of devices based on said therapy recommendation since any such controlling is part of the therapy and can therefore be regarded as a therapy recommendation*) and

controlling operation of the drug delivery device or one of the therapy devices based on the therapy recommendation (*par. 38, 46, 95-98, 112*).

1.3.6 The subject-matter of claim 1 therefore differs from the disclosure of D1 in:

the clinical context data is received from a health information system

first a clinical prediction is generated for the patient based on a combination of the clinical context data and the high fidelity data and then the therapy recommendation is generated based on said clinical prediction

1.3.7 **Analysis of the technical character of the distinguishing features**

1.3.8 The distinguishing features – *when taken in isolation* – are all non-technical because they constitute a mathematical method.

1.3.9 Features which are non-technical when taken in isolation may nevertheless contribute to the technical character of an invention if, in the context of the invention, they contribute to producing a technical effect serving a technical purpose (G-VII, 5.4, second paragraph).

1.3.10 In the present case, the distinguishing features do not contribute to the technical character of the invention for the reasons following.

1.3.11 Purpose(s) and effect(s)

1.3.12 The purpose which these distinguishing features *allegedly* serve in the context of claim 1 is to control operation of a therapy device.

This purpose is considered technical.

1.3.13 However, the claim is not sufficiently limited to ensure that this technical purpose is *actually* served by the distinguishing features over the whole claim scope, for the following reasons:

1.3.14 The distinguishing features are defined at such a level of abstraction/in such vague terms that no technical effect can be derived from them over their whole scope. In particular, it is not specified nor apparent from common knowledge, how a clinical prediction for the patient can be generated based on a combination of the clinical context data and the high fidelity data and furthermore, how a therapy recommendation can be generated from said clinical prediction. This objection is particularly severe because of the broad scope of the clinical context data and the high fidelity data, as well as the therapy recommendation, since if the distinguishing features were defined sufficiently, common knowledge would have to enable the skilled person to implement the distinguishing features over an enormous range of different types of data and fur any possible therapy recommendation on which the control of operation of therapy devices can be based.

1.3.15 It follows that in the context of present claim 1 the distinguishing features, which are per se non-technical, cannot derive a technical character from the technical purpose identified in point 1.3.12 as they do not actually contribute to serve it. These features do thus not contribute to the technical character of the invention.

1.3.16 **Conclusion regarding inventive step**

1.3.17 As claim 1 does not comprise any feature making a technical contribution over the teaching of D1, it cannot be regarded as involving an inventive step within the meaning of Article 33(3) PCT (G-VII, 5.4(iii)(b)).

1.3.18 **Further remarks**

1.3.19 Notwithstanding the aforementioned objection of lack of an inventive step, the applicant's attention is drawn to the fact that claim 1 appears to contain more features – disclosed in D1– which do not contribute to the technical character

of the claimed invention and cannot, therefore, support the presence of an inventive step in the sense of Article 33(3) PCT (see Guidelines G-VII, 5.4 in combination with G-II, 3):

1.3.20 controlling operation of the drug delivery device or one of the therapy devices based on the therapy recommendation (while the control of operation is technical, basing it on the therapy recommendation, i.e. the process of computing the controlling command from the therapy recommendation, is part of a mathematical method)

1.4 Should the applicant rely on any of these features when providing arguments for the presence of an inventive step, it will be necessary to substantiate why said feature(s) is/are considered by the applicant to make a technical contribution over D1, i.e. to contribute to a technical effect for solving a technical problem over D1.

1.5 The same as for claim 1 applies, mutatis mutandis, to claims 15 and 20 with the additional notion that applying physiological models to generate a clinical prediction merely details the mathematical method of claim 1 without overcoming the objection laid out in 1.3.14 and that the therapy devices enumerated in claim 20 merely comprise choices among known alternatives that are within the normal competence of a person skilled in the art.

1.6 The additional subject-matter of claims 2 and 16 is also disclosed by document D1 (*par. 59-62, 127*)

1.7 The additional subject-matter of claims 3-12, 14 and 17-19 comprises choices among known alternatives that are within the normal competence of a person skilled in the art.

1.8 The additional subject-matter of claim 13 comprises minor implementation details that are within the normal competence of a person skilled in the art.

Re Item VIII

Certain observations on the international application

2 The present application does not meet the requirements of Article 6 PCT because claims 1-20 is not clear.

3 The term "high fidelity data" has no established definition in the art and no such definition is given in the claims. While the words of the term, according to common understanding, appear to refer to a high reliability of the data, it is

entirely unclear which real time measurements are considered as "high fidelity data" in the sense of the claims and which are not. For interpreting the claims, the term is interpreted as non-limiting.