

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/EP2020/061813

International filing date (day/month/year)
29.04.2020

Priority date (day/month/year)
03.05.2019

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/24

Applicant
SANOFI

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

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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. 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>3, 4, 6-9</u>
	No: Claims	<u>1, 2, 5, 10-16</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-16</u>
Industrial applicability (IA)	Yes: Claims	<u>1-16</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

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

Reference is made to the following documents:

- D1 WO 2012/046199 A1 (MEIRING HENDRIK [ZA]) 12 April 2012
(2012-04-12)
- D2 US 2004/207385 A1 (GAFNER SIMONE [CH] ET AL) 21 October 2004
(2004-10-21)
- D3 WO 2008/037801 A1 (NOVO NORDISK AS [DK]; MOELLER CLAUS
SCHMIDT [DK]; KVOLSBJERG BO [DK]) 3 April 2008 (2008-04-03)
- D4 EP 0 407 020 A1 (CUMMINS ELECTRONICS [US]) 9 January 1991
(1991-01-09)

Re Item VIII

Certain observations on the international application

Clarity

- 1 The subject-matter of claim 1 is not considered to fulfill the requirements of Art. 6 PCT for the following reason:

Claim 1 defines "...one sensor comprises an interdigital electrode structure...". However, such an "interdigital" structure is considered to require at least two sets of electrodes, with interdigitated (or interleaved, i.e. finger-like) electrodes.

In this sense, solely defining one set of an electrode as interdigitated is considered to be simply wrong. Thus, for the sake of this search, claim 1 is considered as comprising an electrode arranged in a pattern.

In order to comply with Art. 6 PCT, the electrode pattern should have been defined in a technically correct way, such as by claiming and defining a respective second electrode (see for example dependent claim 6).

- 2 The embodiment shown in fig. 13 and described in the respective text passages is not considered to fall within the scope of claim 1, in the sense that it actually discloses a (workable) "interdigitated electrode structure": Electrodes (431, 432) are conductively connected, and not "interdigitated". In fact, as such, the embodiment of fig. 13 is considered to disclose a mere and common strain gauge.

Consequently, dependent claim 7 is not considered to be clear in the sense of Art. 6 PCT.

Re Item V

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

Independent claims 1 & 16

- 3 Taking account of the above clarity objection, the present application does not meet the requirements of Article 33(1) PCT because the subject-matter of claim 1 is not new within the meaning of Article 33(2) PCT:
- 3.1 Document D1 discloses a rotation sensing arrangement for an injection device (p. 1, li. 5-6), the rotation sensing arrangement comprising:
- a first member and a second member, wherein the first member and the second member are rotatable relative to each other with regard to an axis of rotation (34 & 38, p. 8, li. 16-19, also p. 10, li. 9-19),
 - at least one signal generator arranged on the first member, at least one sensor arranged on the second member, wherein the at least one sensor comprises an interdigital electrode structure configured to generate an electrical signal in response to a movement of the at least one signal generator relative to the sensor (p. 8, li. 7-16, also p. 10, li. 24-28),
 - a processor connected to the at least one sensor and operable to calculate an angle of rotation of the first member relative to the second member on the basis of the electrical signal (p. 10, li. 20-22, also fig. 4, 54).
- 3.2 Document D2 also discloses a rotation sensing arrangement for an injection device (par. 2 & 3), the rotation sensing arrangement comprising:
- a first member and a second member, wherein the first member and the second member are rotatable relative to each other with regard to an axis of rotation (par. 7),

- at least one signal generator arranged on the first member, at least one sensor arranged on the second member, wherein the at least one sensor comprises an interdigital electrode structure configured to generate an electrical signal in response to a movement of the at least one signal generator relative to the sensor (par. 9 & 12, 17, also fig. 6a),
 - a processor connected to the at least one sensor and operable to calculate an angle of rotation of the first member relative to the second member on the basis of the electrical signal (par. 7).
- 3.3 The subject-matter of claim 1 is also not considered to be novel over document D3, see in particular p. 6, li. 3-15, fig. 7, 21, 22 (Art. 33(1) and (2) PCT).
- 3.4 For the sake of completeness, document D4 is also mentioned as an example of a rotation sensing arrangement suitable for an injection device, over which the subject-matter of claim 1 is not considered to be inventive (see figs. 4 & 5, col. 1, li. 1-4, li. 46-49, Art. 33(3) PCT).
- 4 Since independent method claim 16 solely defines the logical use of the arrangement of claim 1, its subject-matter is -mutatis mutandis- also not considered to be novel over any of the documents D1, D2 or D3 (Art. 33(1) and (2) PCT).

Dependent claims 2-15

- 5 Document D1 further discloses:
- Claim 5: P. 10, li. 24-28.
 - Claim 7: P. 8, li. 12.
 - Claim 13: P. 8, li. 12.
 - Claim 14: P. 7, li. 29-31, also figs. 5 & 7.
 - Claim 15: P. 3, li. 9-25, p. 5, li. 4-6,
- 5.1 Document D3 further discloses:
- Claim 2: fig. 7, 21, 22.

- 5.2 The subject-matter of claim 10 to 12 appears to be disclosed in document D2, see for example fig. 6a.
- 5.3 Consequently, the subject-matter of claims 2, 5, 7 and 10-15 is not considered as being novel (Art. 33(1) and (2) PCT).
- 6 The subject-matter of claim 6 is disclosed in document D4 (Art. 33(3) PCT).
- 7 Claims 3, 4, 8 and 9 appear to relate to well known design choices in the field of sensor design, and are therefore not considered as providing any surprising technical effect, i.e. provide a basis for a potentially inventive step (Art. 33(3) PCT).

Re Item VII

Certain defects in the international application

- 8 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents D1 to D4 have not been mentioned in the description, nor are these documents identified therein.
- 9 Any independent claim should have been drafted in the two-part form in accordance with Rule 6.3(b) PCT, 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).