

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.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.
PCT/EP2024/055543

International filing date (day/month/year)
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C07H17/00 C07H17/02 C07H19/01

Applicant
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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

Knaus-Reinbold, S

Telephone No. -0



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.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),
 - ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
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. 14-18

because:

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

☐ 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. 14-18

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

☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in the form, language and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13~~ter~~.1(a).

☒ 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>4, 7-13</u>
	No: Claims	<u>1-3, 5, 6</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-13</u>
Industrial applicability (IA)	Yes: Claims	<u>1-13</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

Re Item III

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

- 1 Claims 1 and 14 have been drafted as separate independent product claims, they relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter.

There is no clear distinction between the independent claims because of overlapping scope. There are so many claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines 9.19 and 9.25).

Thus, the subject-matter of this claims 14 to 18 has not been searched and consequently no examination was carried out for those claims (Rule 66.1 (e) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 2 Reference is made to the following documents:

- | | |
|----|--|
| D1 | US 2016/166774 A1 (LEARY JEFFREY M [US]) 16 June 2016 (2016-06-16) |
| D2 | EP 2 397 174 A2 (BECTON DICKINSON CO [US]) 21 December 2011 (2011-12-21) |
| D3 | US 2015/164856 A1 (BIRTE REICHE D; HAAG) 18 June 2015 (2015-06-18) |
| D4 | EP 2 554 199 A1 (TERUMO CORP [JP]) 6 February 2013 (2013-02-06) |
| D5 | US 5 512 054 A (MORNINGSTAR RANDY L [US]) 30 April 1996 (1996-04-30) |
| D6 | US 9 566 388 B1 (JONES COREY DEWAYNE [US]) 14 February 2017 (2017-02-14) |

Novelty Article 33(2) PCT

- 3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1 to 3,5 and 6** does not seem to be new in the sense of Article 33(2) PCT.
- 4 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) a system (100) for administering a liquid pharmaceutical composition to a patient (figure 1 to 17), the system comprising a syringe, wherein the syringe comprises:
- a barrel (112) comprising a hollow elongated member including an open barrel forward end and an open barrel rear end, the hollow elongated member comprising:
 - a first portion (114) that extends from the open barrel forward end to a transition section disposed along the hollow elongated member, the first portion having a first cross-sectional dimension; and
 - a second portion (112) that extends from the transition section to the open barrel rear end, the second portion having a second cross-sectional dimension that is greater than the first cross-sectional dimension; and
 - a plunger (142) comprising an elongated member including a plunger forward end and a plunger rear end; wherein:
 - the plunger (142) and the barrel (112) are dimensioned such that a portion of the plunger including the plunger forward end is insertable within the hollow elongated member of the barrel at the open barrel rear end (figure 3),
 - and the plunger is extendible within the barrel until the plunger forward end engages with an internal surface portion of the hollow elongated member at the barrel forward end (figure 4);
 - receipt of liquid pharmaceutical composition (medicament) within the barrel of the syringe via the open barrel forward end is limited to a volume defined within the first portion of the barrel, wherein the volume is adjustable by adjusting a displacement of the plunger forward end away from the barrel forward end; and
 - a surface wall section of the plunger includes indicia (146) comprising a dosage scale that indicates the volume of the liquid pharmaceutical

composition received within the first portion of the barrel based upon a corresponding displacement of the plunger forward end away from the barrel forward end.

Therefore the subject matter of claim 1 is not novel over document D1.

5 Moreover document D1 shows the technical feature of claims 2,3,5 and 6. (paragraph 52, figure 1 to 6)

6 Furthermore document D2 reveals the technical feature of claims 1,2,3,5 and 6. (figure 1 to 24, syringe, barrel (221), first portion (121), second portion (124), indicia (246)).

Inventive Step Article 33(3) PCT

7 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 4 and 7 to 13** does not seem to involve an inventive step in the sense of Article 33(3) PCT.

8 Document D1 is the closest prior art. In **claim 4** a slight constructional change in the system of claim 1 is suggested which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance. Consequently, the subject-matter of these claims also appears to lack an inventive step.

9 Feature in **claims 7 to 13** is described in document D3 as providing the same advantages as in the present application, to have a liquid pharmaceutical formulation of SGLT-2 inhibitors which is particularly useful to ensure appropriate administration of such compounds in a safe and efficacious manner to the patient.

The skilled person would therefore regard it as a normal option to include this feature in the system described in document D1 in order to solve the problem posed. Consequently, the subject-matter of these claims also appears to lack an inventive step.

Re Item VII

Certain defects in the international application

10 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1-D6 are not mentioned in the description, nor are these documents identified therein.

- 11 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 (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 12 The features of claim 1 to 13 are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

Clarity Article 6 PCT

- 13 The application does not meet the requirements of Article 6 PCT, because **claim 1** is not clear.

It is clear from claim 5 that features :

- the dosage scale on the surface wall section of the plunger comprises a **plurality of marks aligned in a direction that corresponds with a lengthwise dimension of the plunger**; and
- in operation, the volume of the liquid pharmaceutical composition received within the first portion of the barrel in response to displacement of the plunger forward end away from the barrel forward end is indicated by alignment of a corresponding mark of the dosage scale with an exterior surface of the barrel at the barrel rear end.

are essential to the definition of the invention.

The combination of the features above seem to be at least necessary to perform the function described and to achieve the result claimed by the applicant. If any of the features was missing, the system would not work, and there are no other possibilities disclosed in the description.

- 14 Claim 1 does not meet the requirements of Article 6 PCT because the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.
- **the plunger is extendible within the barrel until the plunger forward end engages with an internal surface portion of the hollow elongated member at the barrel forward end**;
 - receipt of liquid pharmaceutical composition within the barrel of the

syringe via the open barrel forward end is limited to a volume defined within the first portion of the barrel, **wherein the volume is adjustable by adjusting a displacement of the plunger forward end away from the barrel forward end;**