

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 234275-12-ko	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2024/055543	International filing date (<i>day/month/year</i>) 4 March 2024 (04-03-2024)	(Earliest) Priority Date (<i>day/month/year</i>) 6 March 2023 (06-03-2023)
Applicant BOEHRINGER INGELHEIM VETMEDICA GMBH		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out 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))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established by this Authority to read as follows:

SYSTEMS FOR DELIVERY OF LIQUID PHARMACEUTICAL COMPOSITIONS IN PARTICULAR COMPRISING ONE OR MORE SGLT-2 INHIBITOR(S)

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☒ none of the figures is to be published with the abstract

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 14 - 18
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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A. CLASSIFICATION OF SUBJECT MATTER		
INV.	A61K31/70	A61P9/00
	C07H7/04	A61P1/18
	C07H17/02	C07H19/01
	A61K9/00	A61M5/31
	A61K38/00	C07H15/203
	A61P3/00	C07H17/00
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61K A61P C07H A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/166774 A1 (LEARY JEFFREY M [US]) 16 June 2016 (2016-06-16)	1 - 6
Y	paragraph [0022] - paragraph [0120]; figures 1-18	7 - 13

X	EP 2 397 174 A2 (BECTON DICKINSON CO [US]) 21 December 2011 (2011-12-21)	1, 3, 5, 6
	paragraph [0042] - paragraph [0114]; figures 1-24	

Y	US 2015/164856 A1 (BIRTE REICHE D; HAAG-DIERGARTEN S ET AL.) 18 June 2015 (2015-06-18)	7 - 13
	paragraph [0103] - paragraph [0348]; figures 1-15	

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☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 21 May 2024		Date of mailing of the international search report 10/06/2024
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Knaus-Reinbold, S

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 2 554 199 A1 (TERUMO CORP [JP]) 6 February 2013 (2013-02-06) paragraph [0009] - paragraph [0098]; figures 1-7 -----	1 - 13
A	US 5 512 054 A (MORNINGSTAR RANDY L [US]) 30 April 1996 (1996-04-30) page 3, line 11 - page 5, line 2; figures 1-6 -----	1 - 13
A	US 9 566 388 B1 (JONES COREY DEWAYNE [US]) 14 February 2017 (2017-02-14) column 3, line 25 - column 8, line 27; figures 1-10 -----	1 - 13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2024/055543

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016166774 A1	16-06-2016	AU 2015362808 A1	29-06-2017
		CA 2970150 A1	23-06-2016
		EP 3233165 A2	25-10-2017
		US 2016166774 A1	16-06-2016
		US 2017000952 A1	05-01-2017
		WO 2016100202 A2	23-06-2016
EP 2397174 A2	21-12-2011	CA 2743207 A1	18-12-2011
		CA 3195444 A1	18-12-2011
		EP 2397174 A2	21-12-2011
		EP 3791909 A1	17-03-2021
		ES 2847879 T3	04-08-2021
		ES 2953787 T3	16-11-2023
		JP 5882607 B2	09-03-2016
		JP 2012000470 A	05-01-2012
		US 2011313397 A1	22-12-2011
		US 2021213208 A1	15-07-2021
US 2015164856 A1	18-06-2015	AU 2014364999 A1	19-05-2016
		AU 2020201551 A1	19-03-2020
		AU 2021269354 A1	16-12-2021
		AU 2023237139 A1	19-10-2023
		BR 112016011564 B1	09-02-2021
		CA 2930034 A1	25-06-2015
		CA 3163455 A1	25-06-2015
		CA 3167193 A1	25-06-2015
		CN 105828815 A	03-08-2016
		CN 111494357 A	07-08-2020
		DK 3082829 T3	03-05-2021
		DK 3862003 T3	29-01-2024
		EA 201600467 A1	30-12-2016
		EP 3082829 A1	26-10-2016
		EP 3862003 A1	11-08-2021
		EP 4285995 A2	06-12-2023
		ES 2859905 T3	04-10-2021
		FI 3862003 T3	28-12-2023
		HR P20231694 T1	15-03-2024
		HU E053906 T2	28-07-2021
		JP 6293897 B2	14-03-2018
		JP 6774449 B2	21-10-2020
		JP 2016540790 A	28-12-2016
		JP 2018090606 A	14-06-2018
		KR 20160096196 A	12-08-2016
		KR 20220103814 A	22-07-2022
		KR 20240017116 A	06-02-2024
		LT 3862003 T	27-12-2023
		PL 3082829 T3	06-09-2021
		PL 3862003 T3	02-04-2024
		RS 64990 B1	31-01-2024
		SI 3862003 T1	29-02-2024
		US 2015164856 A1	18-06-2015
		US 2020197352 A1	25-06-2020
		US 2023140631 A1	04-05-2023
		WO 2015091313 A1	25-06-2015
EP 2554199 A1	06-02-2013	AU 2011233190 A1	11-10-2012
		BR 112012024454 A2	03-10-2017
		CN 102844062 A	26-12-2012

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Information on patent family members

International application No

PCT/EP2024/055543

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
		EP 2554199 A1	06-02-2013	
		JP 5719522 B2	20-05-2015	
		JP 2011212185 A	27-10-2011	
		SG 183991 A1	30-10-2012	
		TW 201132376 A	01-10-2011	
		US 2013079729 A1	28-03-2013	
		WO 2011122221 A1	06-10-2011	

US 5512054	A	30-04-1996	AU 693671 B2	02-07-1998
			CA 2218734 A1	21-11-1996
			DE 69608954 T2	19-10-2000
			EP 0814857 A1	07-01-1998
			JP 3097922 B2	10-10-2000
			JP H10506557 A	30-06-1998
			US 5512054 A	30-04-1996
			WO 9636379 A1	21-11-1996

US 9566388	B1	14-02-2017	US 9566388 B1	14-02-2017
			WO 2017176359 A1	12-10-2017

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 14-18

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).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.3), should the problems which led to the Article 17(2) PCT declaration be overcome.