

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:

Zhao, Yong
Eli Lilly and Company
P.O. Box 6288
Indianapolis, IN 46206-6288
ETATS-UNIS D'AMERIQUE

RECEIVED

SEP 11 2023

LILLY LEGAL

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 22895	Date of mailing (day/month/year) 31 August 2023 (31-08-2023)
International application No. PCT/US2023/021641	International filing date (day/month/year) 10 May 2023 (10-05-2023)
Applicant ELI LILLY AND COMPANY	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34 chemin des Colombettes, 1211 Geneva 20, Switzerland

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of **18 months from the priority date**, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within **22 months from the priority date**, the applicant may request that a **supplementary international search** be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
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Authorized officer

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 22895	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2023/021641	International filing date (day/month/year) 10 May 2023 (10-05-2023)	(Earliest) Priority Date (day/month/year) 11 May 2022 (11-05-2022)
Applicant ELI LILLY AND COMPANY		

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 4 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:

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

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2023/021641

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/20 A61K9/14 A61K31/437 A61K9/28 A61P3/04
A61P3/10

ADD.

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

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, CHEM ABS 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 2019/225604 A1 (YOSHINO HITOSHI [JP] ET AL) 25 July 2019 (2019-07-25)	1-3, 5, 7, 10, 12-18
Y	abstract; claims 1-13; examples 67, 162-163, Test examples 1-4; tables 2-5,	1-3, 5, 7, 10, 12-18
A	1-4; compound 67 page 93 paragraph [0305]	4, 6, 8, 9, 11, 19-51
X	JP 2019 099571 A (CHUGAI PHARMACEUTICAL CO LTD) 24 June 2019 (2019-06-24)	1-3, 5, 7, 10, 12-18
Y	page 105, paragraph 404; examples 162-163, test examples 1-4; compound 67	1-3, 5, 7, 10, 12-18
A	paragraph [0185]	4, 6, 8, 9, 11, 19-51
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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

23 August 2023

Date of mailing of the international search report

31/08/2023

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2

NL - 2280 HV Rijswijk

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Authorized officer

Madalinska, K

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2023/021641

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KAWAI TAKAHIRO ET AL: "Structural basis for GLP-1 receptor activation by LY3502970, an orally active nonpeptide agonist", PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES , vol. 117, no. 47 24 November 2020 (2020-11-24), pages 29959-29967, XP093070947, ISSN: 0027-8424, DOI: 10.1073/pnas.2014879117 Retrieved from the Internet: URL:http://dx.doi.org/10.1073/pnas.2014879117	1-3, 5, 7, 10, 12-18
A	abstract; figure 1 page 29966, column 2, paragraph Compound Formulation - page 29967, column 1, paragraph 1 -----	4, 6, 8, 9, 11, 19-51

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2023/021641

Patent document cited in search report	Publication date	Patent family member(s)	Publication date		
US 2019225604 A1	25-07-2019	AU 2017330733 A1	14-03-2019		
		AU 2020223687 A1	10-09-2020		
		AU 2022205222 A1	04-08-2022		
		BR 112019005322 A2	02-07-2019		
		CA 3038479 A1	29-03-2018		
		CL 2019000663 A1	26-07-2019		
		CN 109790161 A	21-05-2019		
		CO 2019002595 A2	29-03-2019		
		CR 20190149 A	27-08-2019		
		DO P2019000074 A	31-05-2019		
		EA 201990518 A1	30-12-2019		
		EA 202190802 A2	30-07-2021		
		EC SP19020228 A	30-06-2019		
		EP 3517538 A1	31-07-2019		
		EP 4134367 A1	15-02-2023		
		IL 264945 A	30-05-2019		
		IL 287166 A	01-12-2021		
		JP 6567778 B2	28-08-2019		
		JP 6957564 B2	02-11-2021		
		JP 7280929 B2	24-05-2023		
		JP 2019203015 A	28-11-2019		
		JP 2022003087 A	11-01-2022		
		JP 2023100963 A	19-07-2023		
		JP WO2018056453 A1	11-07-2019		
		KR 20190039591 A	12-04-2019		
		MA 46286 A	31-07-2019		
		NZ 751725 A	26-03-2021		
		PE 20190709 A1	17-05-2019		
		PH 12019500659 A1	16-12-2019		
		SA 519401409 B1	07-04-2022		
		SG 11201901565V A	28-03-2019		
		TN 2019000054 A1	15-07-2020		
		TW 201827426 A	01-08-2018		
		UA 125586 C2	27-04-2022		
		US 2019225604 A1	25-07-2019		
		US 2021017176 A1	21-01-2021		
		WO 2018056453 A1	29-03-2018		
		ZA 201901070 B	30-06-2021		

		JP 2019099571 A	24-06-2019	NONE	

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

PCT/US2023/021641

TITLE: GLP1 TABLET COMPOSITIONS

APPLICANT: ELI LILLY AND COMPANY

IPC CLASSIFICATION: A61K9/20, A61K9/14, A61K31/437, A61K9/28, A61P3/04, A61P3/10

EXAMINER: Madalinska, K

CONSULTED DATABASES: CA, REG, EPDOC, NPL

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61K9/485, A61K31/437, A61K9/141, A61K9/2054, A61K9/2886, A61P3/04, A61P3/10, A61K9/146

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

a composition, tablet, spray-dried dispersion, 3-[(1S,2S)-1-[5-[(4S)-2,2-dimethyloxan-4-yl]-2-[(4S)-2-(4-fluoro-3,5-dimethylphenyl)-3-[3-(4-fluoro-1-methylindazol-5-yl)-2-oxoimidazol-1-yl]-4-methyl-6,7-dihydro-4H-pyrazolo[4,3-c]pyridine-5-carbonyl]indol-1-yl]-2-methylcyclopropyl]-4H-1,2,4-oxadiazol-5-one, GLP1RA, orforglipron, LY-3502970, OWL-833, pH modifier, calcium carbonate, magnesium carbonate, sodium bicarbonate, sodium carbonate, magnesium hydroxide, calcium hydroxide, magnesium oxide, diabetes, weight management