

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

Vorndran-Jones, Macharri R.
Eli Lilly and Company
P.O. Box 6288
Indianapolis, IN 46206-6288
ETATS-UNIS D'AMERIQUE

RECEIVED

OCT 16 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 30144	Date of mailing (day/month/year) 6 October 2023 (06-10-2023) FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2023/068925	International filing date (day/month/year) 23 June 2023 (23-06-2023)
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



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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 30144	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2023/068925	International filing date (day/month/year) 23 June 2023 (23-06-2023)	(Earliest) Priority Date (day/month/year) 30 June 2022 (30-06-2022)
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 6 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.

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out 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.
2. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this report has been established to the extent that a meaningful search could be carried out without a WIPO Standard ST.26 compliant sequence listing.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2023/068925

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/00 A61K38/26 A61K47/02 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, BIOSIS, CHEM ABS Data, EMBASE, 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 2020/023040 A1 (BENSON CHARLES T [US] ET AL) 23 January 2020 (2020-01-23) claims 50-51, 55-56 -----	1-98
X	US 2019/388502 A1 (CORVARI VINCENT JOHN [US] ET AL) 26 December 2019 (2019-12-26) claims paragraph [0037]; tables 3-4 ----- -/--	1-98

☒ 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

27 September 2023

Date of mailing of the international search report

06/10/2023

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

Lemarchand, Aude

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2023/068925

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Anonymous: "PRESCRIBING INFORMATION. MOUNJARO TM (tirzepatide) Injection, for subcutaneous use Initial U.S. Approval: 2022", 1 May 2022 (2022-05-01), May 2022 (2022-05), XP093086105, Retrieved from the Internet: URL: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s0001b1.pdf page 23/28 page 22/28 page 2/28, paragraph 1 and 2.1.	1-98
X	JASTREBOFF ANIA M. ET AL: "Tirzepatide Once Weekly for the Treatment of Obesity", THE NEW ENGLAND JOURNAL OF MEDICINE, vol. 387, no. 3, 6 June 2022 (2022-06-06), pages 205-216, XP093086223, US ISSN: 0028-4793, DOI: 10.1056/NEJMoa2206038 abstract table 2 figure 1	1-98
X	JUAN PABLO FRIAS ET AL: "Efficacy and tolerability of tirzepatide, a dual glucose-dependent insulintropic peptide and glucagon-like peptide-1 receptor agonist in patients with type 2 diabetes: A 12-week, randomized, double-blind, placebo-controlled study to evaluate different dose-escalation regimens", DIABETES, OBESITY AND METABOLISM, BLACKWELL SCIENCE, GB, vol. 22, no. 6, 11 February 2020 (2020-02-11), pages 938-946, XP072205210, ISSN: 1462-8902, DOI: 10.1111/DOM.13979 abstract ----- -/--	1-98

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2023/068925

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DAHL DOMINIK ET AL: "Effect of Subcutaneous Tirzepatide vs Placebo Added to Titrated Insulin Glargine on Glycemic Control in Patients With Type 2 Diabetes : The SURPASS-5 Randomized Clinical Trial", JAMA THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, vol. 327, no. 6, 8 February 2022 (2022-02-08), page 534, XP055918557, US ISSN: 0098-7484, DOI: 10.1001/jama.2022.0078 Retrieved from the Internet: URL:http://dx.doi.org/10.1001/jama.2022.0078> abstract	1-98
X,P	WO 2022/272019 A2 (GILA THERAPEUTICS INC [US]) 29 December 2022 (2022-12-29) claim 20	1-98

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2023/068925

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2020023040	A1	23-01-2020	AU 2019309796 A1	21-01-2021
			AU 2022291585 A1	02-02-2023
			BR 112020026372 A2	23-03-2021
			CA 3107344 A1	30-01-2020
			CN 112512633 A	16-03-2021
			EP 3826716 A1	02-06-2021
			IL 280258 A	01-03-2021
			JP 2021533094 A	02-12-2021
			JP 2022130686 A	06-09-2022
			KR 20210024583 A	05-03-2021
			MA 53390 A	02-06-2021
			SG 11202100112Y A	25-02-2021
			TW 202019460 A	01-06-2020
			US 2020023040 A1	23-01-2020
			US 2021338781 A1	04-11-2021
			WO 2020023382 A1	30-01-2020

US 2019388502	A1	26-12-2019	AR 115542 A1	27-01-2021
			AU 2019289110 A1	21-01-2021
			AU 2022279524 A1	02-02-2023
			BR 112020023452 A2	23-02-2021
			CA 3103469 A1	26-12-2019
			CL 2020003359 A1	25-06-2021
			CN 112312926 A	02-02-2021
			CR 20200634 A	21-01-2021
			DK 3810201 T5	21-08-2023
			EA 202092713 A1	05-04-2021
			EC SP20082717 A	29-01-2021
			EP 3810201 A2	28-04-2021
			EP 4257185 A2	11-10-2023
			FI 3810201 T3	17-08-2023
			IL 279504 A	31-01-2021
			IL 295433 A	01-10-2022
			JP 6896945 B2	30-06-2021
			JP 2021167314 A	21-10-2021
			JP 2021506952 A	22-02-2021
			KR 20210010572 A	27-01-2021
			KR 20230058172 A	02-05-2023
			LT 3810201 T	25-07-2023
			MA 52965 A	28-04-2021
			PE 20210049 A1	08-01-2021
			PH 12020552215 A1	28-06-2021
			PT 3810201 T	04-07-2023
			RS 64288 B1	31-07-2023
			SG 11202012744U A	28-01-2021
			SI 3810201 T1	31-08-2023
			TW 202015717 A	01-05-2020
			US 2019388502 A1	26-12-2019
			US 2022273762 A1	01-09-2022
			WO 2019245893 A2	26-12-2019

WO 2022272019	A2	29-12-2022	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/US2023/068925

TITLE: TIRZEPATIDE COMPOSITIONS AND USE

APPLICANT: ELI LILLY AND COMPANY

IPC CLASSIFICATION: A61K9/00, A61K38/26, A61K47/02, A61P3/04, A61P3/10

EXAMINER: Lemarchand, Aude

CONSULTED DATABASES: BIOSIS, CA, EMBASE, EPODOC, MEDLINE, NPL, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61K9/0019, A61K38/26, A61K47/02, A61P3/04, A61P3/10

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

A Pharmaceutical composition comprising tirzepatide, or a pharmaceutically acceptable salt thereof; NaCl; and sodium phosphate; wherein the tirzepatide, or pharmaceutically acceptable salt concentration is from about 40 mg/mL to about 60 mg/mL or 2.5 mg/mL
treatment of diabetes (type 2), obesity