

PATENT COOPERATION TREATY

PC072879A
PMID582224

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:

Zielinski, Bryan C.
PFIZER INC.
100 Route 206 North
Mail Stop: SOM-PPK4-LLA-403
Peapack, New Jersey 07977
ETATS-UNIS D'AMERIQUE

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

(PCT Rule 44.1)

Date of mailing (day/month/year)	
11 October 2023 (11-10-2023)	
Applicant's or agent's file reference PC072879A	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IB2023/056844	International filing date (day/month/year) 30 June 2023 (30-06-2023)
Applicant PFIZER INC.	

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
Tel. (+31-70) 340-2040
Fax: (+31-70) 340-3016

Authorized officer

BENITEZ SIERRA, Olga María
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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 PC072879A	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/IB2023/056844	International filing date (day/month/year) 30 June 2023 (30-06-2023)	(Earliest) Priority Date (day/month/year) 5 July 2022 (05-07-2022)
Applicant PFIZER INC.		

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**,

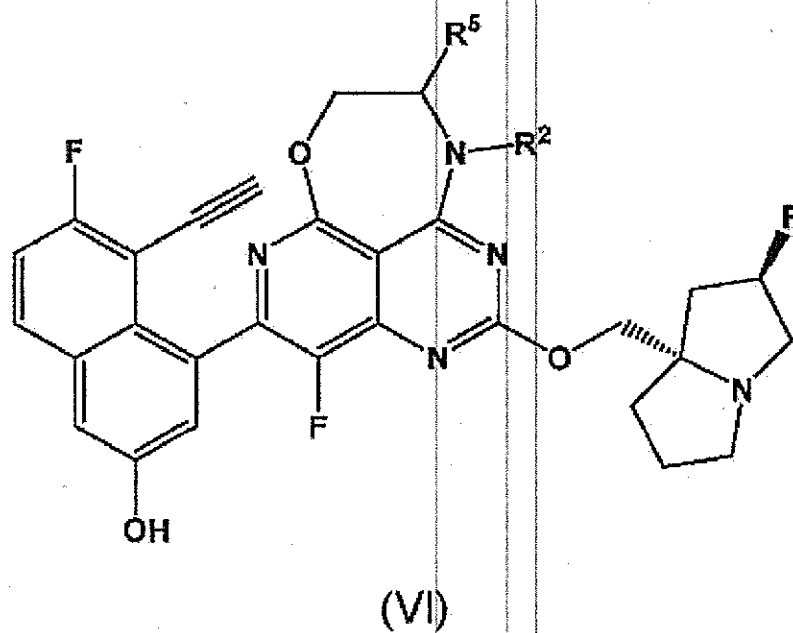
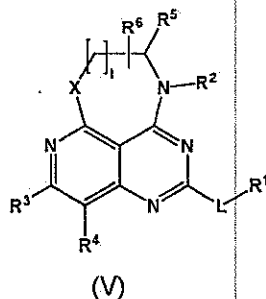
- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

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

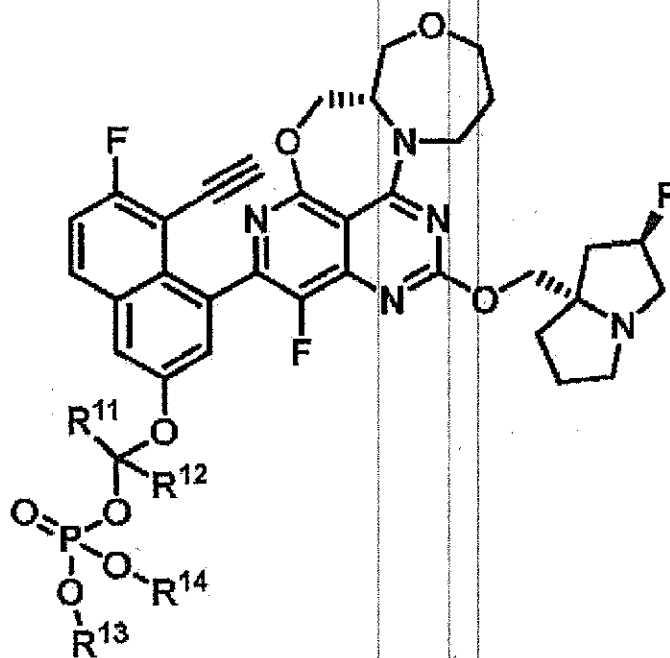
- a. the figure of the **drawings** to be published with the abstract is Figure No. _____
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
- b. ☒ none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

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The invention relates to compounds of Formula (V)-(VII), or pharmaceutically acceptable salts thereof, to their use in medicine; to compositions containing them; to processes for their preparation; and to intermediates used in such processes. The compounds the present invention may be useful in the treatment, prevention, suppression and amelioration of cancers, diseases, or disorders.



Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)



(VII)

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2023/056844

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61P35/00 C07D519/00 A61K31/55

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)
C07D

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.
A	FELL JAY B. ET AL: "Identification of the Clinical Development Candidate MRTX849, a Covalent KRASG12C Inhibitor for the Treatment of Cancer", JOURNAL OF MEDICINAL CHEMISTRY, vol. 63, no. 13, 6 April 2020 (2020-04-06), pages 6679-6693, XP055788094, US ISSN: 0022-2623, DOI: 10.1021/acs.jmedchem.9b02052 Retrieved from the Internet: URL: http://pubs.acs.org/doi/pdf/10.1021/acs.jmedchem.9b02052> the whole document ----- --/--	1-32

☒ 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

28 September 2023

Date of mailing of the international search report

11/10/2023

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

Hanisch, Inken

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2023/056844

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2022/132200 A1 (MIRATI THERAPEUTICS INC [US]) 23 June 2022 (2022-06-23) the whole document; in particular the claims, the examples and table 5 -----	1-32
X,P	WO 2023/046135 A1 (JACOBIO PHARMACEUTICALS CO LTD [CN]) 30 March 2023 (2023-03-30) the whole document; in particular the claims and compounds 1-6, 9, 13, 15, 19, 23 and 24 -----	1-32
X,P	WO 2022/199587 A1 (MEDSHINE DISCOVERY INC [CN]) 29 September 2022 (2022-09-29) the whole document, in particular the claims and the figures -----	1-3, 6-11, 14, 15, 20-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2023/056844

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2022132200 A1	23-06-2022	AU 2021401232 A1 CA 3198885 A1 EP 4262807 A1 IL 303446 A US 2023072276 A1 WO 2022132200 A1	22-06-2023 23-06-2022 25-10-2023 01-08-2023 09-03-2023 23-06-2022
WO 2023046135 A1	30-03-2023	NONE	
WO 2022199587 A1	29-09-2022	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/IB2023/056844

TITLE: CONDENSED PYRIDO4,3-DPYRIMIDINE COMPOUNDS

APPLICANT: PFIZER INC.

IPC CLASSIFICATION: A61P35/00, C07D519/00, A61K31/55

EXAMINER: Hanisch, Inken

CONSULTED DATABASES: REAXYS, WPI, NPL

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC:

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

inhibitors of KRAS G12C, KRAS G12D and KRAS G12V receptors; anticancer agents; condensed pyrido-pyrimidine compounds; KRAS, C-K-RAS, CFC2, K-RAS2A, K-RAS2B, K-RAS4A, K-RAS4B, KI-RAS, KRAS1, KRAS2, NS, NS3, RALD, RASK2, K-ras, KRAS proto-oncogene, GTPase, c-Ki-ras2, OES, c-Ki-ras, K-Ras 2, 'C-K-RAS, K-Ras, Kirsten RAT Sarcoma virus, Kirsten Rat Sarcoma virus

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/B2023/056844

International filing date (day/month/year)
30.06.2023

Priority date (day/month/year)
05.07.2022

International Patent Classification (IPC) or both national classification and IPC
INV. A61P35/00 C07D519/00 A61K31/55

Applicant
PFIZER INC.

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:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Hanisch, Inken
Telephone No. -0



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2023/056844

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. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2023/056844

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 1-32
No: Claims

Inventive step (IS) Yes: Claims 1-32
No: Claims

Industrial applicability (IA) Yes: Claims 1-32
No: Claims

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)
and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

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 V.

Reference is made to the following documents:

- D1 FELL JAY B. ET AL: "Identification of the Clinical Development Candidate MRTX849, a Covalent KRASG12C Inhibitor for the Treatment of Cancer", JOURNAL OF MEDICINAL CHEMISTRY, vol. 63, no. 13, 6 April 2020 (2020-04-06), pages 6679-6693, XP055788094, US
ISSN: 0022-2623, DOI: 10.1021/acs.jmedchem.9b02052
Retrieved from the Internet:
URL: <http://pubs.acs.org/doi/pdf/10.1021/acs.jmedchem.9b02052>
- D2 WO 2022/132200 A1 (MIRATI THERAPEUTICS INC [US]) 23 June 2022

Claims 21-24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT.

The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

Novelty

The compounds of current formulae (V) and (VII) as claimed in current claims 1 and 16 as well as those specific compounds not falling within either general formula claimed in current claim 19 are considered to be novel over D1 and D2: They essentially differ from said prior art due to their (optionally further fused) seven- or eight-membered heterocycle fused to the pyridopyrimidine bicycle. By consequence, all claims are novel over D1 and D2.

Inventive Step

Both D1 and D2 disclose pyridopyrimidine derivatives which have anticancer activity due to their KRASG12C/Pan-KRAS inhibiting ability (see e.g. D1 abstract, D2 table 5 on page 725) and can be considered to be the closest prior art.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/IB2023/056844

Currently claimed compounds of formula (V) as well as the additional compounds claimed in independent claim 19 have been shown to inhibit KRAS G12C, KRAS G12D and KRAS G12V (see table 3 on current page 101: compounds 27 and 33 re formula (V) as well as compounds 23, 24, 26, 29, 31 and 32 re current claim 19, see also item VIII below). They essentially differ from the disclosure of D1 and D2 due to their at least one seven- or eight-membered heterocycle as claimed being peri-fused to the pyridopyrimidine core. The skilled person looking for further anticancer agents which are able to inhibit at least KRASG12C had no incentive to arrive at the current solution from either of D1 or D2. As a consequence, the current solution is considered to be non-obvious over D1 and D2.

Re Item VI.

Certain documents cited

Certain published documents

Application No	Publication date	Filing date	Priority date
WO 2023/ 046135 A1 (D3)	30-03-2023	26-09-2022	27-09-2021
			18-03-2022
			29-06-2022
			21-09-2022
WO 2022/199587 A1 (D4)	29-09-2022	22-03-2022	24-03-2021
			18-09-2021
			28-01-2022
			25-02-2022

D3 which has been filed in-between the currently claimed second and third priority dates (of 21-08-2022 and 11-10-2022, respectively) has been published in-between the currently claimed third and fourth priority (of 11-10-2022 and 18-05-2023, respectively) and claims three priority dates which are earlier than the currently claimed earliest priority date (of 05-07-2022). D3, which discloses general formulae and specific

compounds of the desired activity anticipating current subject-matter (see in particular the claims and compounds 1-6, 9, 13, 15, 19, 23 and 24 of D3), may thus become relevant for novelty at least involving all of its subject-matter entitled to one of its first three priority dates (of D3) as well as for all current subject-matter not entitled to one of the first two currently claimed priority dates. Furthermore, D3 may be considered to be highly relevant for inventive step for all current subject-matter not entitled to one of the first three currently claimed priority dates.

D4 which has been filed prior to the currently claimed earliest priority date (of 05-07-2022) and published in-between the currently claimed second and third priority dates (of 21-08-2022 and 11-10-2022, respectively) is considered to disclose subject-matter which could be relevant for the assessment of inventive step at least for those current compounds which are not entitled to one of the first two currently claimed priority dates, and which are considered to be a novel selection from the disclosure of claim 1 of D4, having the same activity.

Re Item VII.

Current claims 22 and 23 are drafted as independent claims, however, their subject-matter is considered to fall within the scope of current claim 21.

It is noted that the description contains incorporations by reference (see p.103) and a passage relating to the spirit of the invention (see p.103).

Re Item VIII.

Claim 19 contains one specific compound which is considered to fall within the scope of current claim 1, see the first compound in line 2 of compounds, i.e. current compound 27. In order to avoid casting any doubt on the scope of protection sought this compound should not be subject of an independent claim but of a dependent claim.

The scope of current claim 30 is considered not to be clearly defined as the therapeutic application of the molecules is functionally defined by a mechanism of action (i.e. by their capability of inhibiting KRAS G12C, KRAS G12D and KRAS G12V receptors), which does not allow any practical application in the form of a defined, real treatment of a pathological condition (disease).

The scope of the invention needs to be clearly defined by the claims and them to be fully supported by the description (Article 6 PCT). In this respect, two issues are noted:

- First, the description contains subject-matter much broader than what is claimed, see e.g. formulae (I)-(IV), embodiments E1-E62 and corresponding examples, as well as prodrugs or metabolites (see e.g. pages 36, 37) and as such casts doubts on the scope of the actual invention. This opinion exclusively relates to the subject-matter currently claimed.
- Second, current claim 31 appears to lack a true counterpart in the description. It is noted that it differs from embodiment E93 (see current page 25).

**Filing a demand
for international
preliminary
examination**

In principle, the **WO/ISA** will be considered to be the written opinion of the International Preliminary Examining Authority (**IPEA**). Where the **WO/ISA** issued by the **EPO** as **ISA** gives a positive opinion on the international application and the invention to which it relates, filing a demand with the **EPO** as **IPEA** would normally be unnecessary, since a positive IPRP would anyway be established by the **IB** based on the **WO/ISA** (see also further below).

If the applicant wishes to file a demand (for example, to allow him to argue his case in international preliminary examination with regard to objections raised in a negative **WO/ISA** before the **IPEA** issues an **IPEP**), this must be done before expiration of **3 months after the date of mailing of the ISR and WO/ISA** or **22 months after priority date**, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the **IPEA**, normally at the same time as filing the demand (Rule 66.1(b) PCT) or within the time limit set for reply to any written opinion issued during international preliminary examination by the **IPEA**.

If a demand is filed at the **EPO** as **IPEA** and no comments/amendments have been received by the time the **EPO** starts drawing up the **IPEP** (Rule 66.4bis PCT), the **WO/ISA** will be transformed by the **IPEA** into an **IPEP** (also called the **IPRP (Chapter II)** which would merely reflect the content of the **WO/ISA** (OJ 10/2011, 532). The demand can still be withdrawn (Art. 37 PCT).

Please also note that, when filing amendments under Art. 34 PCT, such amendments shall be accompanied by a letter which identifies the amendments made and also the basis for the amendments in the application as originally filed (Rule 66.8(a) PCT). Failure to comply with this requirement may result in the amendments being ignored in the **IPEP (IPRP (Chapter II))**, see Rule 70.2(c-bis) PCT.

**Filing a request
for supplementary
international
search**

The applicant may, with the **IB**, file a request for **supplementary international search** under Rule 45bis.1 PCT. The present **ISR** and **WO/ISA** may also be taken into account in the execution of that supplementary international search, provided that these are available to the Authority charged with this task before it starts the supplementary search (Rule 45bis.5 PCT).

This kind of request **cannot be filed specifying the ISA** who did the **international search**.

More information on this topic can be found in the **PCT Applicant's Guide**, Chapter 8 (<http://www.wipo.int/pct/en/guide/ip08.html>).

**End of the
international
phase**

Where no demand is filed, at the end of the international phase, the **IB** will transform the **WO/ISA** into the **IPRP (PCT Chapter I)** (Rule 44bis PCT), which will then be transmitted together with possible informal comments to the designated Offices. Where a demand is filed, the **WO/ISA** is not transformed into an **IPRP (Chapter I)** by the **IB**, but rather the **IPEA** will establish an **IPEP**, (the **IPEP** is the same as the **IPRP (PCT Chapter II)**, see Rule 70.15 PCT).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO/ISA)

General information

For all international applications, the competent International Searching Authority (ISA) will establish an international search report (ISR) accompanied by a written opinion of the International Searching Authority (WO/ISA). The WO/ISA may be responded to by

- filing informal comments with the International Bureau of WIPO (IB) (where no demand for international preliminary examination (demand) is filed)
- filing amendments under Art. 19 PCT (this can be done whether or not a demand is filed)
- filing amendments under Art. 34 PCT and/or formal observations in response to objections raised in the WO/ISA (where a demand is actually filed)

This document explains these possibilities.

Filing informal comments

After receipt of the ISR and WO/ISA, the applicant may file informal comments on the WO/ISA, directly with the IB (see International Search and Preliminary Examination Guidelines 2.15). These will be communicated to the designated/elected Offices, together with the International Preliminary Report on Patentability (IPRP) at 30 months from the priority date.

Amending claims under Art. 19 PCT

The applicant may file amended claims under Art. 19 PCT, directly with the IB by the later of the following dates:

- 2 months from the date of mailing of the ISR and the WO/ISA
- 16 months from the priority date

However, any such amendment received by the IB after the expiration of the applicable time limit shall be considered to have been received on time by the IB, if it reaches it before the technical preparations for international publication have been completed (the 15th day prior to the date of publication, see PCT Applicant's Guide, International Phase, 9.013).

For further information, please see Rule 46 PCT as well as form PCT/ISA/220.

Please also note that, when filing amended claims under Art. 19 PCT, such amendments shall be accompanied by a letter identifying the amendments made and also the basis for the amendments in the application as originally filed (Rule 46.5(b) PCT). Where a demand is filed, failure to comply with this requirement may result in the amendments being ignored in the International Preliminary Examination Report (IPER), see Rule 70.2(c-bis) PCT.

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