

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

SAHR, Robert N.
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
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) 13 September 2023 (13-09-2023)	
Applicant's or agent's file reference P1139.70011WO00	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IB2023/055592	International filing date (day/month/year) 31 May 2023 (31-05-2023)
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

GIEL-BARRAGÁN RAMOS, Cecilia
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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 P1139.70011WO00	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB2023/055592	International filing date (day/month/year) 31 May 2023 (31-05-2023)	(Earliest) Priority Date (day/month/year) 31 May 2022 (31-05-2022)
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 5 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/IB2023/055592

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/IB2023/055592

A. CLASSIFICATION OF SUBJECT MATTER

INV. **C07K16/22 A61P11/00 A61P9/00**
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)

C07K A61K

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, 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 2014/056902 A1 (SHIMIZU KIYOSHI [JP] ET AL) 27 February 2014 (2014-02-27) the whole document	1-27, 41-67, 72, 73
X	JP 2017 025011 A (KYOWA HAKKO KIRIN CO LTD) 2 February 2017 (2017-02-02) the whole document	1-27, 41-67, 72, 73
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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

6 September 2023

Date of mailing of the international search report

13/09/2023

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

Covone-van Hees, M

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2023/055592

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	TU LY ET AL: "Selective BMP-9 inhibition partially protects against experimental pulmonary hypertension", CIRCULATION RESEARCH, vol. 124, no. 6, 15 March 2019 (2019-03-15), pages 846-855, XP055834375, US ISSN: 0009-7330, DOI: 10.1161/CIRCRESAHA.118.313356 the whole document -----	1-27, 41-75
X	AYUMI SEKINE ET AL: "OA4658: Contribution of BMP9 to Pulmonary Arterial Hypertension", EUROPEAN RESPIRATORY JOURNAL; ERS INTERNATIONAL CONGRESS 2017 ABSTRACTS; MILAN, ITALY; SEPTEMBER 9-13, 2017, EUROPEAN RESPIRATORY SOCIETY, GB, vol. 50, no. Suppl 61, 1 January 2017 (2017-01-01), page OA4658, XP009529612, ISSN: 0903-1936, DOI: 10.1183/1393003.CONGRESS-2017.OA4658 the whole document -----	1-27, 41-75

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2023/055592

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014056902 A1	27-02-2014	CA 2874117 A1	09-01-2014
		CN 104411720 A	11-03-2015
		EP 2868667 A1	06-05-2015
		ES 2720401 T3	22-07-2019
		HK 1209769 A1	08-04-2016
		JP 6298762 B2	20-03-2018
		JP WO2014007198 A1	02-06-2016
		KR 20150030675 A	20-03-2015
		TW 201406781 A	16-02-2014
		US 2014056902 A1	27-02-2014
		WO 2014007198 A1	09-01-2014
JP 2017025011 A	02-02-2017	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/IB2023/055592

TITLE: ANTI-BMP9 ANTIBODIES AND METHODS OF USE THEREOF

APPLICANT: PFIZER INC.

IPC CLASSIFICATION: C07K16/22, A61P11/00, A61P9/00

EXAMINER: Covone-van Hees, M

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

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC:

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

human anti-BMP9 neutralising antibodies, prevent binding to receptor type II and some weakly also to receptor I, effective in the treatment of pulmonary hypertension

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

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/IB2023/055592

International filing date (day/month/year)
31.05.2023

Priority date (day/month/year)
31.05.2022

International Patent Classification (IPC) or both national classification and IPC
INV. C07K16/22 A61P11/00 A61P9/00

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
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Covone-van Hees, M
Telephone No. -0



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2023/055592

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. 28-40(completely); 1-27, 41-75(partially)

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. 28-40(completely); 1-27, 41-75(partially) are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☒ the claims, or said claims Nos. 28-40(completely); 1-27, 41-75(partially) are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ 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 13ter.1(a).
- ☒ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2023/055592

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>1-27, 41-75(all partially)</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-27, 41-75(all partially)</u>
Industrial applicability (IA)	Yes: Claims	<u>1-27, 41-75(all partially)</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 The present application contains 11 independent claims defining the antibodies by reference to the (partial sequences of the) CDRs, VH/VL, HC/LC or plasmid encoding the VH/VL. 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).
 - 1.1 Since the three CDRs of each of the variable domains of the light and heavy chains of an IgG are normally responsible for binding to the antigen, the IgG, in order to be uniquely defined by its structure only and have its characteristic binding specificity, needs to be defined by the number of CDRs required for its binding to fulfil the requirements of 6 PCT.
 - 1.2 Additionally, in view of the available prior art, disclosing anti-BMP9 antibodies and the different properties of the exemplified antibodies, it is not clear what is the common novel and inventive technical feature(s). A formal non-unity may be raised in the regional phase.
 - 1.3 The search was based on the subject-matter that, as far as can be understood, could reasonably be expected to be claimed later in the procedure, and the corresponding claims, namely claims 2 ii-ix and 4 defining the antibodies by the 6 CDRs. Accordingly independent claims referring to the antibodies defined by VH and VL or HC and LC are also covered by the search.
- 2 Additionally claims 28-40 define the antibody by reference to the binding residues. This definition is highly unclear and requires an undue burden to test and reproduce antibodies binding to the same residues. Additionally, due to the use of an unusual parameter to define the antibodies, a meaningful comparison with the prior art is not possible. The claims therefore lack clarity, support and disclosure to such an extent that they are not searched.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3 Cited documents

D1: US 2014/056902

D2: JP 2017 025011

D3: Tu Ly ET AL: (2019), XP055834375

D4: AYUMI SEKINE ET AL: (2017), XP009529612

3.1 Content of the cited documents

D1 and D2: produce neutralising muring anti-BMP9 (see whole doc).

D3 and D4 inhibit BMP9 with neutralising anti-BMP9 antibodies to treat PAH. The sequence of the antibodies are not disclosed in the documents (see the whole doc).

4 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. Patentability, in particular novelty and inventive step, of claim(s) 67-71,74,75 has been assessed on the basis of a purpose-limited product claim taking into account the alleged effects of the compound/composition.

5 Novelty and Inventive Step (Art.33(2) PCT and Art.33(3) PCT)

5.1 Assessment of novelty and inventive step is done taken into account the limitation of search as explained under item III.

5.2 None of the available prior art documents discloses the CDRs or VH/VL claimed, accordingly claims 1-27,41-75 are novel (Art.33(2) PCT).

5.3 Either D1 or D2 can be taken as closest prior art. Claims 2 and 4 differ over this disclosure by the nature of the sequences defining the CDRs of the antibody. Since no effect has been disclosed as associated with this difference, the problem addressed is defined as how to provide further antibodies binding BMP9. Given that the production of alternative antibodies to those known in the art is routine, the claimed subject-matter lacks inventive step.

- 5.4 Remaining claims do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step: they are mainly standard alternatives in this technical field, which fall within the routine skills of those in the art, and which do not appear to lead to any surprising effects or advantages. Indeed, the use of neutralising antibodies binding to BMP9 to treat PAH is known from D3 and D4.
- 5.5 However, the specific antibodies Ab1076 and Ab732 have been shown in mouse model to effectively treat PAH. While the provision of alternative antibodies is obvious, the provision of antibodies actually showing a potential therapeutic effect is unexpected and would be inventive.

Re Item VII

Certain defects in the international application

- 6 Dependency of claims 5-9 should be checked and corrected, since it makes no sense that these claims depend on claim 4.
- 7 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D4 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

- 8 If an IgG is defined by fewer than the six sequences of its CDRs, the claim will be objected to under Art.6 PCT as a general rule, antibodies need a VH and a VL domain or at least the 3 CDRs of the VH domain and the 3 CDRs of the VL domain for specific antigen binding. The exceptions to this general rule include: camelid, shark or camelised antibodies which are devoid of light chains or engineered single-domain antibodies (sdAbs) derived from heavy-chain antibodies. Therefore, a claim defining an antibody based on only the VH or VL region or on less than 6 CDRs lacks essential technical features. It should also be borne in mind that the lack of essential technical features leads to a lack of inventive step because, usually, the application does not provide any evidence showing that the presence of only a VH or VL chain or of less than 6 CDRs is sufficient to confer antigen binding and to attain the inventive technical effect shown for the entire antibody.

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.

**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 **IPER**), 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 **IPER** (Rule 66.4bis PCT), the **WO/ISA** will be transformed by the **IPEA** into an **IPER** (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 **IPER (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 **IPER**, (the **IPER** is the same as the **IPRP (PCT Chapter II)**, see Rule 70.15 PCT).

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