

PATENT COOPERATION TREATY

PC072794A
PMID 579435

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)		9 February 2023 (09-02-2023)
Applicant's or agent's file reference PC072794A	FOR FURTHER ACTION	See paragraphs 1 and 4 below
International application No. PCT/IB2022/061495	International filing date (day/month/year)	28 November 2022 (28-11-2022)
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	Authorized officer
 European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	FLANTER, Gerda Tel: +49 (0)89 2399-7024

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PC072794A	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB2022/061495	International filing date (day/month/year) 28 November 2022 (28-11-2022)	(Earliest) Priority Date (day/month/year) 1 December 2021 (01-12-2021)
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 3 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:

3-PHENYL-1-BENZOTHIOPHENE-2-CARBOXYLIC ACID DERIVATIVES AS BRANCHED-CHAIN ALPHA KETO ACID DEHYDROGENASE KINASE INHIBITORS FOR THE TREATMENT OF DIABETES, KIDNEY DISEASES, NASH AND HEART FAILURE

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

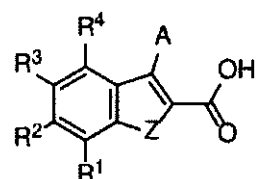
- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

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 present invention refers to compounds of Formula I

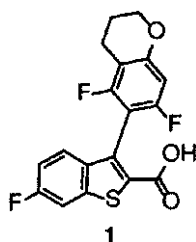


Formula I

as branched-chain alpha keto acid dehydrogenase kinase inhibitors and/or degraders for the treatment of e.g. diabetes, kidney diseases, NASH and heart failure.

Preferred compounds are e.g. 3-phenyl-1-benzothiophene-2-carboxylic acid derivatives.

An exemplary compound is e.g. 3-(5,7-difluoro-3,4-dihydro-2H-1-benzopyran-6-yl)-6-fluoro-1-benzothiophene-2-carboxylic acid (example 1)



The present application discloses the synthesis and characterisation of exemplary compounds as well as pharmacological data thereof.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2022/061495

A. CLASSIFICATION OF SUBJECT MATTER

INV. **C07D333/70 C07D307/85 C07D409/04 A61K31/381 A61K31/343**
A61K31/352 A61P3/10 A61P9/04 A61P13/12 A61P1/16

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 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, 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	SHIH-CHIA TSO ET AL: "Benzothiophene Carboxylate Derivatives as NoAllosteric Inhibitors of Branched-chain alpha-Ketoacid Dehydrogenase Kinase", JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 289, no. 30, 3 June 2014 (2014-06-03), pages 20583-20593, XP055719590, US ISSN: 0021-9258, DOI: 10.1074/jbc.M114.569251 abstract page 20587 - page 20590; figures 1-5; compounds CT2, BT2F -----	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

1 February 2023

Date of mailing of the international search report

09/02/2023

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

Cortés Suárez, José

Information on Search Strategy - Pilot phase (see OJ 2015, A86)

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

Application Number

PCT/IB2022/061495

TITLE: 3-PHENYL-1-BENZOTHIOPHENE-2-CARBOXYLIC ACID DERIVATIVES AS BRANCHED-CHAIN ALPHA KETO ACID DEHYDROGENASE KINASE INHIBITORS FOR THE TREATMENT OF DIABETES, KIDNEY DISEASES, NASH AND HEART FAILURE

APPLICANT: PFIZER INC.

IPC CLASSIFICATION: C07D333/70, C07D307/85, C07D409/04, A61K31/381, A61K31/343, A61K31/352, A61P3/10, A61P9/04, A61P13/12, A61P1/16

EXAMINER: Cortés Suárez, José

CONSULTED DATABASES: WPI, NPL

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: C07D333/70, C07D307/85, C07D409/04, A61P3/10, A61P9/04, A61P13/12, A61P1/16

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

**branched-chain alpha keto acid dehydrogenase kinase inhibitors
(BCKDHA)**

**for the treatment of diabetes, kidney disease, NASH and heart failure
3-phenyl-1-benzothiophene-2-carboxylic acid derivatives**

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

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/B2022/061495

International filing date (day/month/year)
28.11.2022

Priority date (day/month/year)
01.12.2021

International Patent Classification (IPC) or both national classification and IPC

INV. C07D333/70 C07D307/85 C07D409/04 A61K31/381 A61K31/343 A61K31/352 A61P3/10 A61P9/04
A61P13/12 A61P1/16

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

Cortés Suárez, José

Telephone No. +49 89 2399-0



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2022/061495

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 43*bis*.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 13*ter*.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. V Reasoned statement under Rule 43*bis*.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>1-32</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-32</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-32</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 V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents are cited in the present International Search Report:

- D1 SHIH-CHIA TSO ET AL: "Benzothiophene Carboxylate Derivatives as NoAllosteric Inhibitors of Branched-chain alpha-Ketoacid Dehydrogenase Kinase", JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 289, no. 30, 3 June 2014 (2014-06-03), pages 20583-20593, XP055719590, US; ISSN: 0021-9258, DOI: 10.1074/jbc.M114.569251

The present claims 14 to 21 relate to and/or encompass methods of medical treatment and/or medical or diagnostic uses, which are 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 does not recognise as patentable, claims directed to methods of medical treatment or medical uses, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

With entry into the regional phase before the EPO the present claims 14 to 21 must be deleted or rephrased into an allowable form (e.g. "*The compound of claim 1 for use in a method of treatment of ...*").

Novelty (Article 33(2) PCT)

The present compounds differ from the compounds in D1 in the substituent A (page 20587, figure 1, compounds BT2 and BT2F), i.e. in the phenyl or fused phenyl substituent at 3-position of the benzothiophene.

The claimed matter is novel.

Inventive Step (Article 33(3) PCT)

D1 discloses halo-substituted benzothiophene-2-carboxylic acid derivatives as allosteric inhibitors of branched-chain alpha-ketoacid dehydrogenase kinase for the treatment of e.g. diabetes (page 20587 to page 20590, figures 1 to 5, compounds BT2 and BT2F).

D1 is the closest prior art.

The problem of the invention was the provision of new branched-chain alpha keto acid dehydrogenase kinase inhibitors for the treatment of e.g. diabetes, kidney disease, NASH and heart failure.

The present description discloses the synthesis and characterisation of exemplary compounds as well as pharmacological data thereof (e.g. page 87 to page 202; examples 1 to 159; tables 1 to 3 and 4a to 4c; figures 1/3 to 3/3).

The problem seems to have been solved over the whole of the claimed scope.

D1 does not disclose or suggest any benzothiophene-2-carboxylic acid derivatives substituted at 3-position by a phenyl group or a fused phenyl group.

The claimed matter is based on an inventive step.

Re Item VII

Certain defects in the international application

Description

Some parts of the description refer to methods of medical treatment or medical uses as part of the claimed invention (e.g. page 4, line 1; page 5, line 9; page 9, line 12 to page 10, line 20; page 35, line 2).

Some parts of the description refer to structurally undefined "*prodrugs*" as part of the claimed invention (e.g. page 7, line 27; page 12, lines 34 and 36; page 15, line 26).

Some parts of the description refer to structurally undefined "*metabolites*" as part of the claimed invention (e.g. page 15, line 25).

The description contains irrelevant expressions, like e.g.:

- "... *incorporated by reference* ..." (e.g. page 52, line 30; page 53, line 1; page 202, line 4),
- "*It is to be understood that this invention is not limited to specific synthetic methods of making that may of course vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting.*" (e.g. page 6, lines 11 to 14) or
- "*Throughout this application, various publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application for all purposes.*

It will be apparent to those skilled in the art that various modifications and variations can be made without departing from the scope or spirit of the invention. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims." (e.g. page 202, lines 3 to 11).

With entry into the regional phase before the EPO this deficiencies should be fixed by deleting said references to methods of medical treatment, "prodrugs" and "metabolites", and irrelevant expressions.

Re Item VIII

Certain observations on the international application

Lack of Clarity (Article 6 PCT)

The present claim 1 seems to be fully encompassed by the present claim 2.

With entry into the regional phase before the EPO the present claim 2 should be made the new claim 1 and the present claim 1 should be made the new claim 2 containing a reference to new claim 1.

Claims 8 to 13, 30 and 32 lack a reference to claims 1 and 2.

With entry into the regional phase before the EPO the lacking reference should be included into these claims.

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 54*bis* 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 66.4*bis* 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 45*bis*.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 45*bis*.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 44*bis* 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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