สถาบันบริหารจัดการเทคโนโลยีและนวัตกรรม
เลขที่รับ 03366
วันที่ 31 ส.ค. 2564
เวลา 11.43

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
Chitchaeng, Ploypann
Institute for Technology and Innovation Management
MAHIDOL UNIVERSITY
999, Phuttamonthon 4 Road
Salaya
Phuttamonthon
Nakhon Pathom, 73170
THAILANDE

PCT

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 MAHIDOL UNIVERSITY and C	Date of mailing *(day/month/year)* 23 August 2021 (23-08-2021) **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/TH2021/000029	International filing date *(day/month/year)* 4 June 2021 (04-06-2021)
Applicant MAHIDOL UNIVERSITY	

1. [X] 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 90*bis*.1 and 90*bis*.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 45*bis*.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	MARMOY, Valérie Tel: +31 (0)70 340-2366

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
MAHIDOL UNIVERSITY and C		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/TH2021/000029	4 June 2021 (04-06-2021)	29 June 2020 (29-06-2020)
Applicant		
MAHIDOL UNIVERSITY		

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.

[X] 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

   [X] a translation of the international application into EN, 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 43.6*bis*(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

   [X] the text has been established by this Authority to read as follows:

   IMMUNOCHROMATOGRAPHIC METHOD AND KIT FOR DETECTING ANTI-INTERFERON GAMMA ANTIBODY

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

   [X] 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. 2

   [X] 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/TH2021/000029

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N33/543
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)
G01N

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,P	THONGKUM WEERAYA ET AL: "Latticed Gold Nanoparticle Conjugation via Monomeric Streptavidin in Lateral Flow Assay for Detection of Autoantibody to Interferon-Gamma", DIAGNOSTICS, vol. 11, no. 6, 29 May 2021 (2021-05-29), page 987, XP055831872, DOI: 10.3390/diagnostics11060987 see Fig. 1	1-15

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[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
13 August 2021	23/08/2021

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Diez Schlereth, D

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Madariaga L.: "detection of anti-interferon-gamma autoantibodies...", Int. J. Tuberc. Lung Dis., 31 December 1998 (1998-12-31), XP055831882, Retrieved from the Internet: URL:https://www.ingentaconnect.com/content/iuatld/ijtld/1998/00000002/00000001/art00012;jsessionid=4sl3ggae5ells.x-ic-live-01 [retrieved on 2021-08-12] see abstract, p. 63	1-15
Y	YASAMUT UMPA ET AL: "Neutralizing Activity of Anti-interferon-[gamma] Autoantibodies in Adult-Onset Immunodeficiency Is Associated With Their Binding Domains", FRONTIERS IN IMMUNOLOGY, vol. 10, 1 January 1905 (1905-01-01), pages 10-3389, XP055831871, DOI: 10.3389/fimmu.2019.01905 see p. 3	1-15
Y	WO 91/02005 A1 (TURANO ADOLFO [IT]) 21 February 1991 (1991-02-21) see p. 11-12, 27-28	1-15
Y	US 2016/327569 A1 (YIN RAY [US] ET AL) 10 November 2016 (2016-11-10) see [007-009, 012-013, 019, 021, 024, 026-028, 036, 075, 078, 098-099, 102, 113], Figs. 2, 20	1-15
A	WO 2008/073222 A2 (GENZYME CORP [US]; BOEHRINGER HANS [US] ET AL.) 19 June 2008 (2008-06-19) see Figs. 1-2, p. 18	1-15
A	Damián Mainet-González @ ET AL: "Development of a immunochromatographic test with avidin-biotin for the detection of antibodies against antigen e of hepatitis B in human plasma", , 31 October 2007 (2007-10-31), XP055831975, Retrieved from the Internet: URL:https://elfosscientiae.cigb.edu.cu/PDFs/Biotecnol%20Apl/2007/24/3y4/BA00240304TC265-275.pdf [retrieved on 2021-08-13] see p. 266-269, abstract, Fig. 1	1-15

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INTERNATIONAL SEARCH REPORT

International application No
PCT/TH2021/000029

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ZHANG ET AL: "A robust immunoassay for anti-interferon autoantibodies that is highly specific for patients with autoimmune polyglandular syndrome type 1", CLINICAL IMMUNOLOGY, ELSEVIER, AMSTERDAM, NL, vol. 125, no. 2, 16 October 2007 (2007-10-16), pages 131-137, XP022300876, ISSN: 1521-6616, DOI: 10.1016/J.CLIM.2007.07.015 the whole document -----	1-15

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/TH2021/000029

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9102005 A1	21-02-1991	AU 6176690 A	11-03-1991
		DE 69008535 T2	15-12-1994
		EP 0485471 A1	20-05-1992
		IT 1231727 B	21-12-1991
		JP H05500360 A	28-01-1993
		WO 9102005 A1	21-02-1991
US 2016327569 A1	10-11-2016	EP 2452197 A2	16-05-2012
		JP 2012533064 A	20-12-2012
		US 2012220051 A1	30-08-2012
		US 2016041186 A1	11-02-2016
		US 2016327569 A1	10-11-2016
		WO 2011005357 A2	13-01-2011
WO 2008073222 A2	19-06-2008	EP 2126569 A2	02-12-2009
		JP 2010512537 A	22-04-2010
		US 2008138842 A1	12-06-2008
		US 2012107956 A1	03-05-2012
		WO 2008073222 A2	19-06-2008

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/TH2021/000029

TITLE: IMMUNOCHROMATOGRAPHIC METHOD AND KIT FOR DETECTING ANTI-INTERFERON GAMMA ANTIBODY

APPLICANT: MAHIDOL UNIVERSITY

IPC CLASSIFICATION: G01N33/543

EXAMINER: Diez Schlereth, D

CONSULTED DATABASES: NPL, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC:

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
lateral flow immunochromatographic device/assay (sandwich format) for detecting antibodies against interferon-gamma, recombinant interferon-gamma as capture/recognition element in conjugate/test zones and signal amplification by binding the label in the conjugate zone via biotin/avidin system.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.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/TH2021/000029	International filing date *(day/month/year)* 04.06.2021
Priority date *(day/month/year)* 29.06.2020	
International Patent Classification (IPC) or both national classification and IPC INV. G01N33/543	
Applicant MAHIDOL UNIVERSITY	

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 43*bis*.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 notifed the International Bureau under Rule 66.1*bis*(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:	Date of completion of this opinion	Authorized Officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Diez Schlereth, D Telephone No. +31 70 340-0

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/TH2021/000029

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 English , 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:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

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 43*bis*.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 43*bis*.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:

   see separate sheet

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	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

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

and / or

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

see form 210

Re Item II

Priority

The present opinion has been established under the assumption that the claimed priority date (29.06.20) can be acknowledged for the relevant parts of the application.

Re Item V

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

1. Reference is made to the following documents:

D1: W. Thongkum et al (2021)

D2: L. Madariaga et al (1998)

D3: U. Yasamut et al (2019)

D4: WO 91/02005

D5: US 2016/0327569

D6: WO 2008/073222

D7: D. Mainet-González et al (2007)

2. Each one of D2-D4 discloses a heterogeneous immunoassay (and the corresponding device) for detecting anti-IFN-γ antibodies in a sample which is based on the use of a recombinant IFN-γ as capture agent and a IgG antibody labeled with a detectable moiety as reporter agent. The assays/devices of D2-D4 run according to an ELISA (direct and/ or indirect) format (see D2, abstract, p. 63; D3, p. 3; D4, p. 11-12, 27-28).

D2-D4 are silent about immunochromatographic test strips and about the use of biotin:avidin systems as signal amplification means. These features are disclosed in each one of D5-D7.

Each one of D5-D6 discloses a lateral flow immunochromatographic assay/test device for detecting antibodies using the biotin:avidin system as means for signal amplification. In particular, D5 discloses an immunochromatographic device/assay (the so-called LFA bridging assay) for detecting antibodies in which the sample is brought into contact with a mixture of biotinylated antigen and gold nanoparticles conjugated with streptavidin in the conjugate pad and then migrates to a test zone having an the non-biotinylated antigen as capture agent (see [007-009, 012-013, 019, 021, 024, 026-028, 036, 075, 078, 098-099, 102, 113], Figs. 2, 20). A similar format of immunochromatographic

lateral flow assay/device is disclosed in D6 (the so-called indirect lateral flow sandwich assay) which also discloses its application for the detection of antigens, antibodies and other types of analytes (see Figs. 1-2, p. 18).

D7 discloses (apart from an ELISA similar to those of D2-D4) two alternative assay formats in which antibodies in the sample are detected according to an indirect sandwich assay. According to the first format, the sample is brought into contact with a mixture of recombinant antigen and a labeled anti-antigen polyclonal antibody in the conjugate pad and then migrates to a test zone having an anti-antigen monoclonal antibody as capture agent. According to the second format, the sample is brought into contact with a mixture of recombinant antigen, a labeled anti-antigen polyclonal antibody and a biotinylated anti-antigen monoclonal antibody in the conjugate pad and then migrates to a test zone having avidin as capture agent. In both cases, the presence of antibodies against the recombinant antigen in the sample is detected by the absence of detectable signal in the test zone (see p. 266-269, abstract, Fig. 1).

3. Claims 1-15 meet the requirements of Article 33(2) PCT because none of D2-D7 discloses an apparatus and/or a method which requires (A) a first region/zone impregnated with a complex between a biotinylated recombinant IFN-γ and a labeled antibody labeled via binding to the biotin tag and (B) a second region/zone having recombinant IFN-γ immoblized thereon, such that target antibody in the sample can bind to the complex in the first zone and migrate to the second zone.

4. However, claims 1-15 do not meet the requirements of Article 33(3) PCT for the reasons given below.

D5 is considered to be the closest prior art as regards claim 1 because it discloses an apparatus having the most features in common with that of claim 1. The apparatus of claim 1 differs from that of D5 in the particular selection of a recombinant IFN-γ as first/second recognition agent in the conjugate and test zones. The technical effect resulting from this distinguishing feature is that the apparatus is suitable for detecting anti-IFN-γ antibodies. The technical problem to be solved by the present application may be considered to be the provision of alternative means for detecting anti-IFN-γ antibodies.

The solution proposed in claim 1 is not considered to involve an inventive step within the meaning of Article 33(3) PCT for the following reasons. First of all, the skilled person would consider obvious the possibility to use a device/assay according to the format described in D5 for the detection of other target analytes; i.a. other antibodies (this possibility is explicitly mentioned in D5-D6) and to that purpose would adapt accordingly (by selecting a suitable antigen) the reagents used in as first/second recognition agent in the conjugate and test zones. Furthermore, when doing this, in the light of anyone of D2-D4, the skilled person would consider obvious using a

recombinant IFN-γ for that purpose without expecting any surprising technical effect. In this regards, it is to be noted that D6 explicitly mentions the possibility to adapt the format and reagents used in the iindirect lateral flow sandwich assay to other formats, such as the ELISA.

Analogous arguments apply to the subject-matter of claim 12 which relates to a method that is specially adapted to be carried out with the apparatus according to claim 1. Dependent claims 2-11 define slight constructional variations of the apparatus of claim 1 which fall within the customary practice in this technical field and do not result in any unexpected technical effect. The subject-matter of these claims does involve an inventive step within the meaning of Article 33(3) PCT for analogous reasons as discussed above. Analogous arguments apply to dependent claims 13-15.

Re Item VI

Certain documents cited

Should it be found that the claimed priority date cannot be acknowledged when the application enters the regional/national phase, D1 (published on 29.05.21) may be considered relevant for assessing novelty and inventive step of the claimed subject-matter. D1 disclosed an immunochromatographic test strip for detection of autoantibodies against interferon-gamma which is based on the use of a conjugate between recombinant biotinylated IFN-γ and streptavidin labeled with gold nanoparticles as a reporter in the conjugate pad and an IgG antibody as capture reagent in the test zone (see Fig. 1).

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.

BNSDOCID: <XS_____200704010CK_I_>

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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