



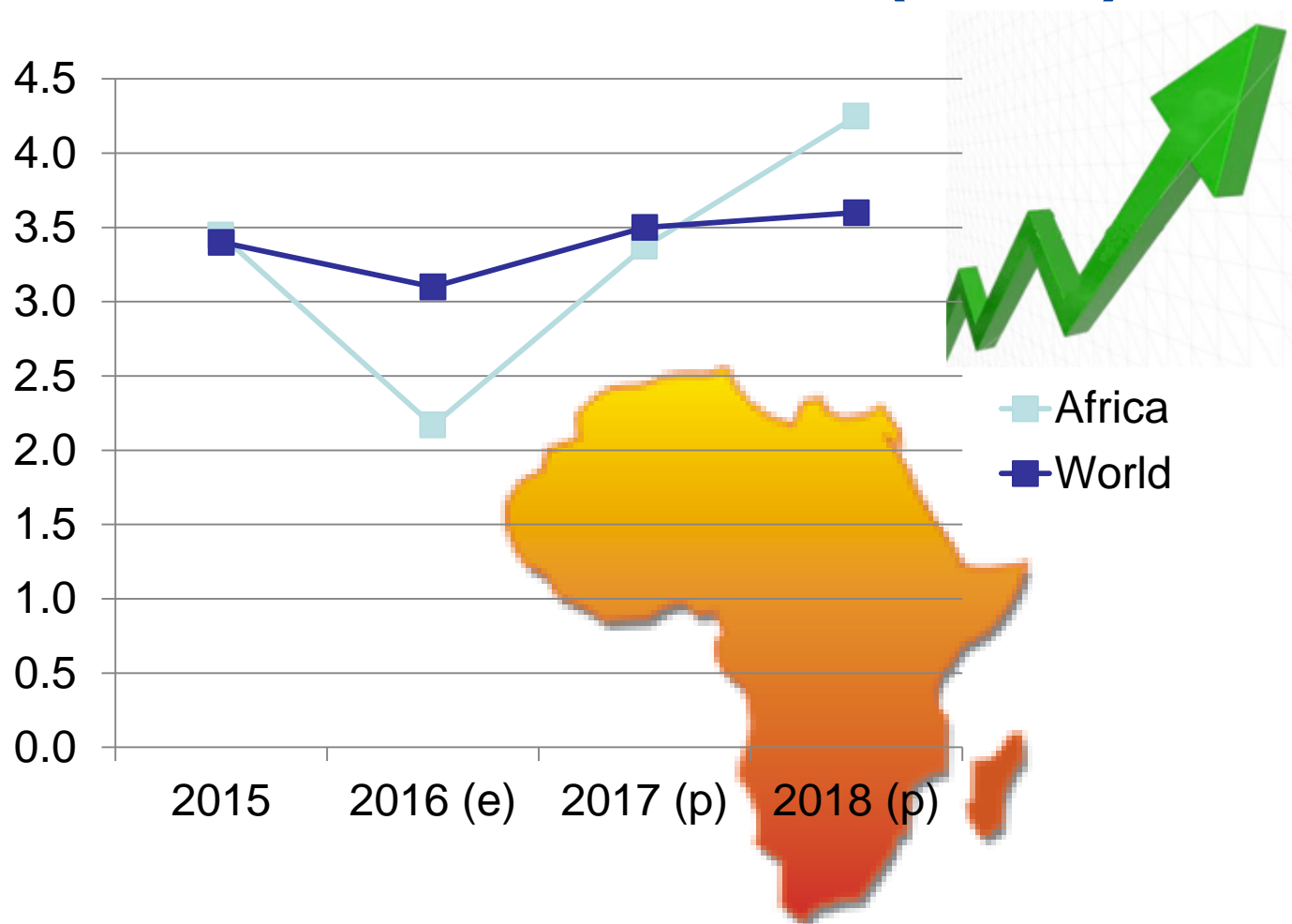
WIPO Sub-Regional Workshop on the PCT National Phase Examination and Utilizing Work Products from Other National Phases

Topic 2: Examination in the PCT International Phase and
Challenges for National Phase Examination

Harare, Zimbabwe
September 18 to 22, 2017

Mr. Ken-Ichiro NATSUME
Director
PCT International Cooperation Division

Growth of Africa (GDP)



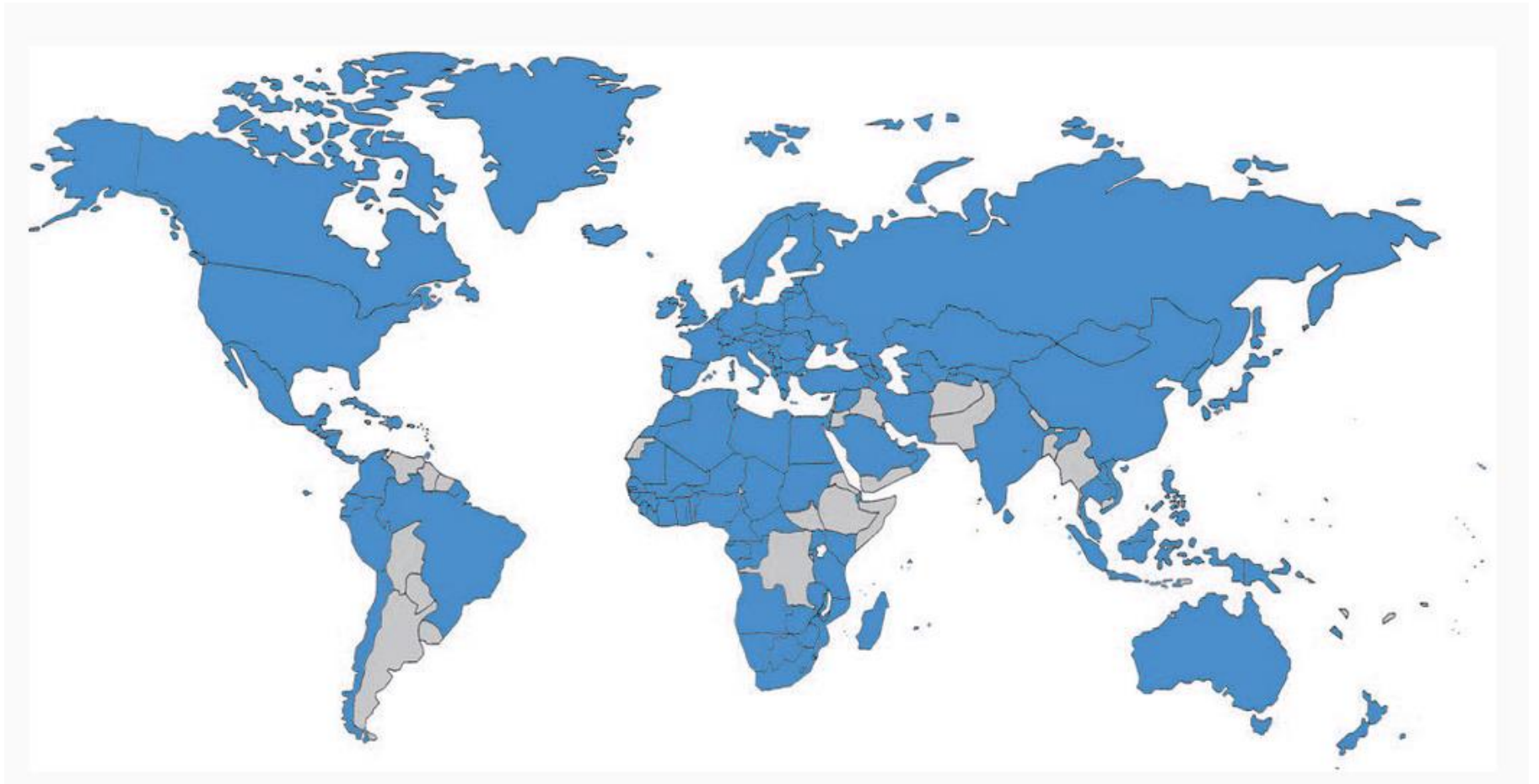
Average growth of patent applications in Africa: 3.1% (2005-2015)

PCT National Phase Entry

	Total	Non-Resident	PCT-NPE
Kenya	193	56	52
Mozambique	102	78	27
ARIPO	780	-	738

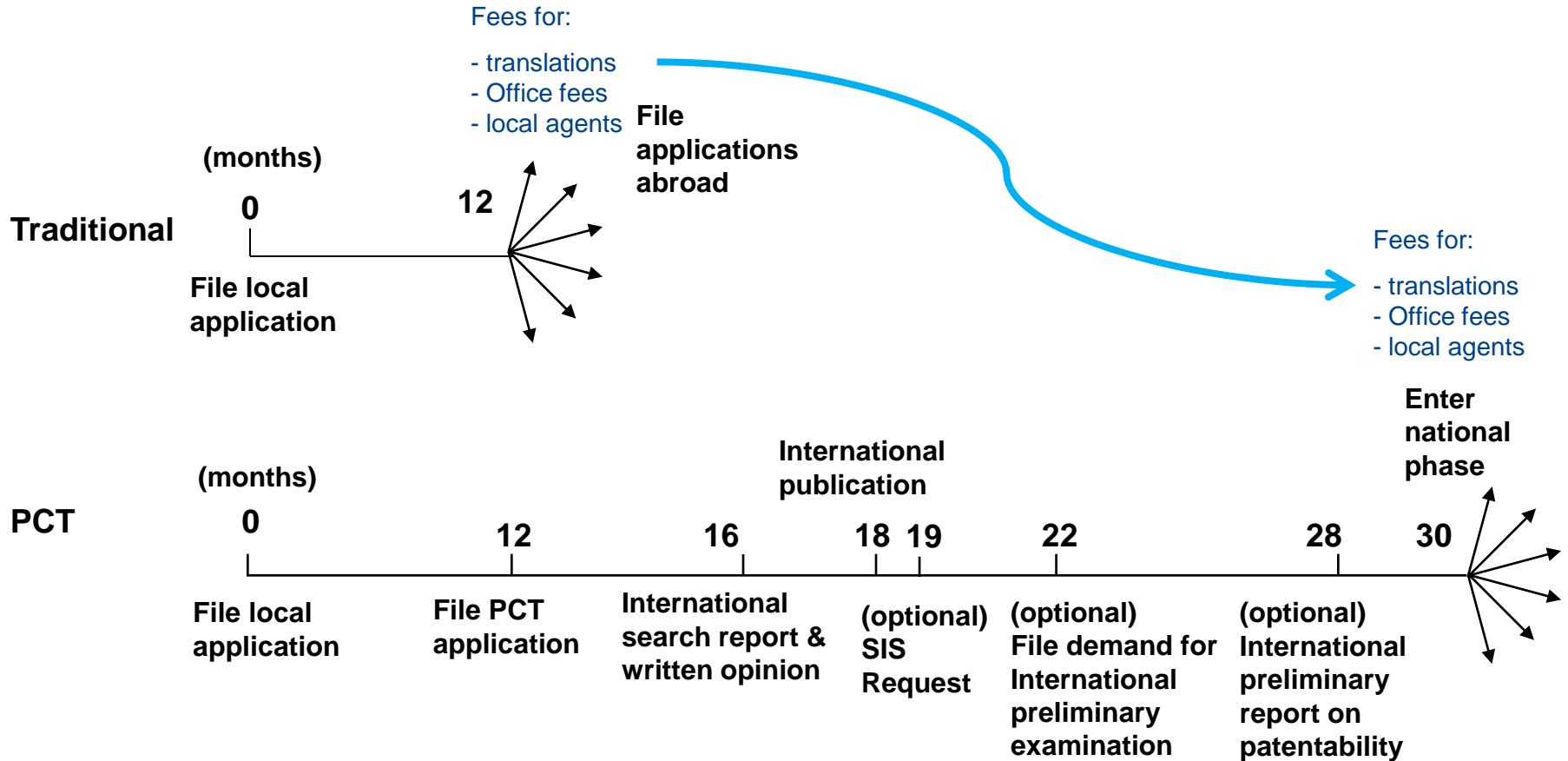
(Based on the statistics from WIPO's Statistical Country Profiles and PCT Yearly Review 2017)

PCT

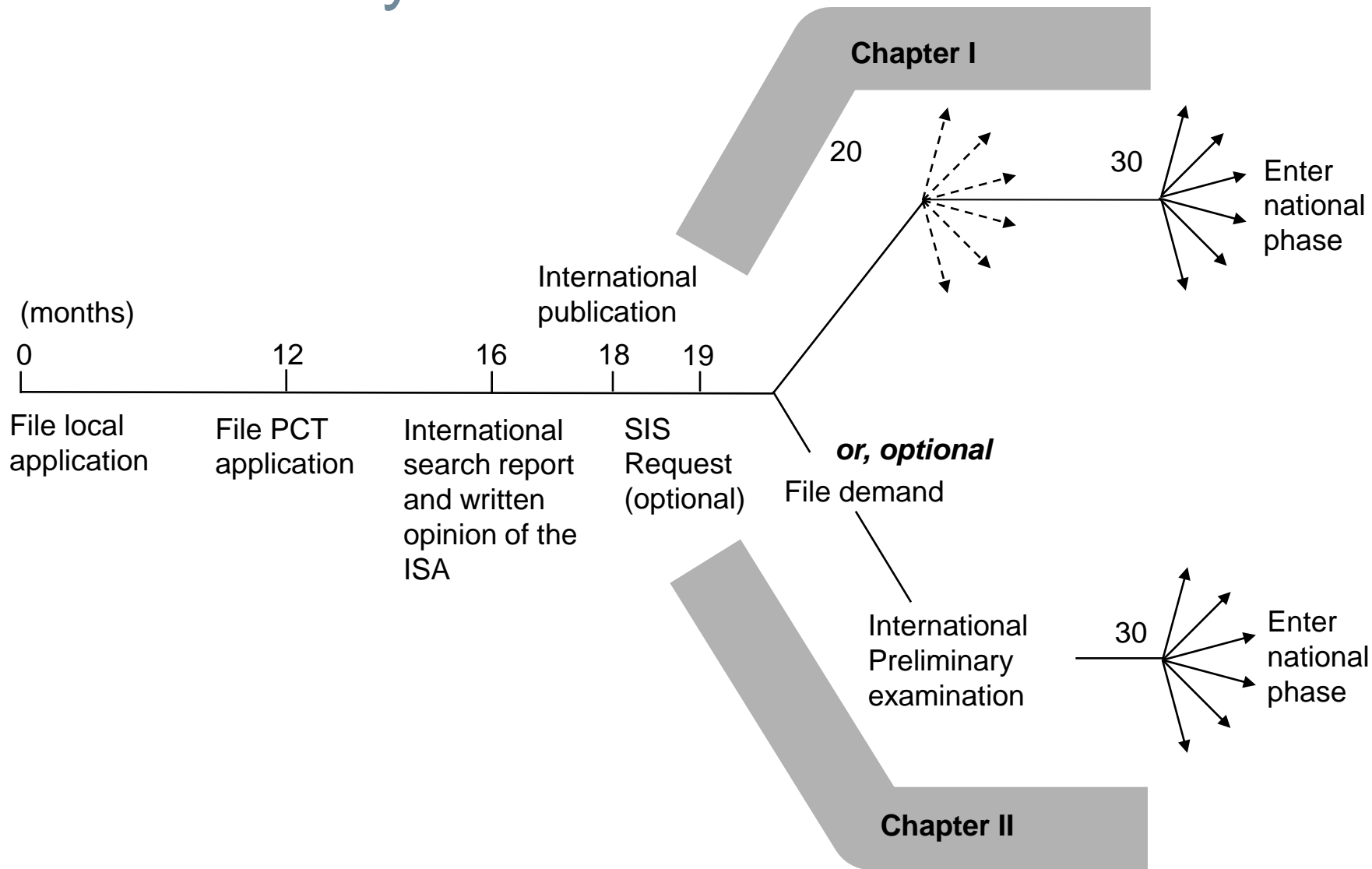


WIPO | PCT
The International
Patent System

Traditional patent system vs. PCT system



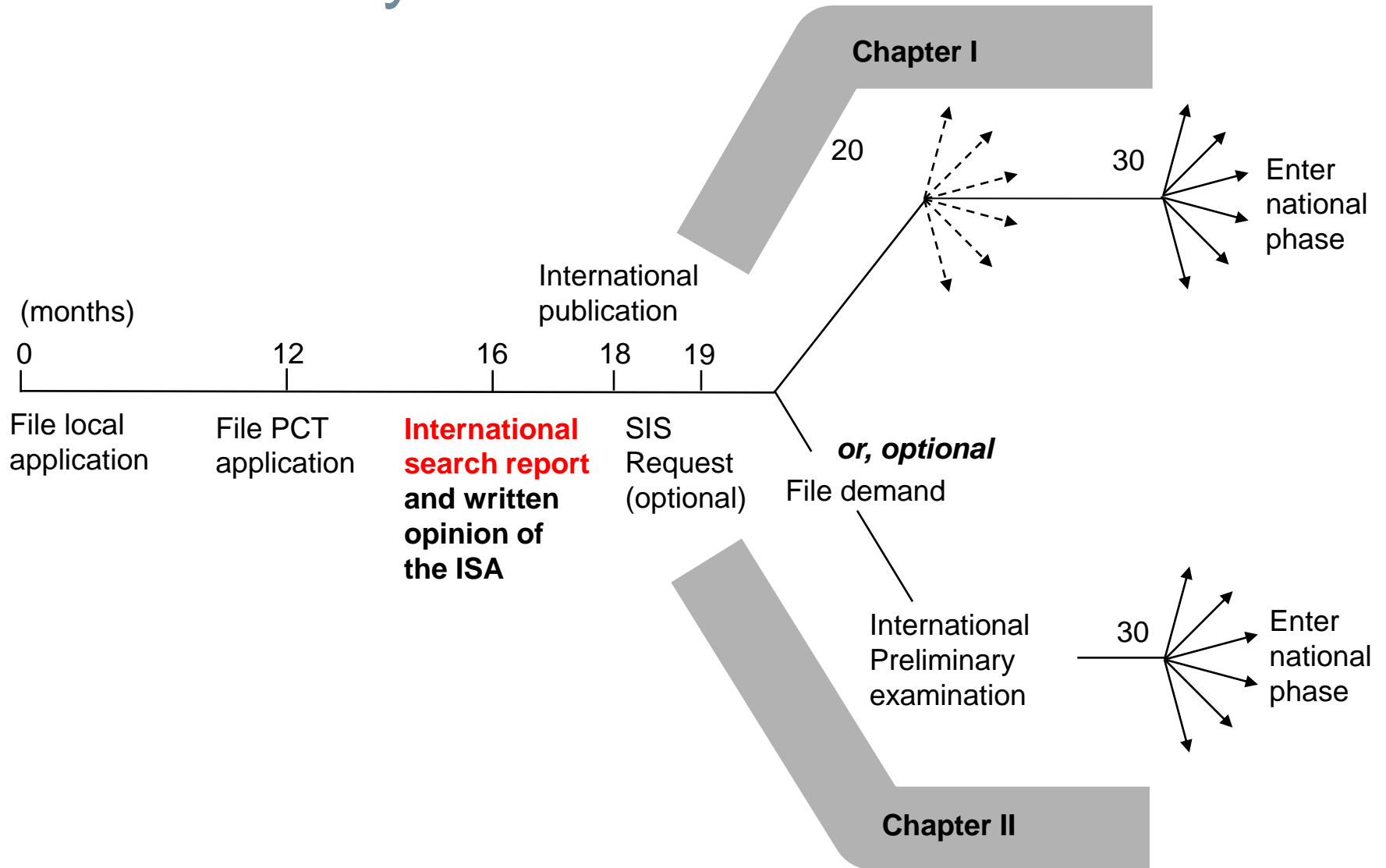
The PCT system



International Search

- International Search Report
- Written Opinion of the International Searching Authority

The PCT system



Prior art for international search (Article 15(2) and Rule 33)

■ Prior art:

- everything which has been made available to the public,
- anywhere in the world,
- by means of written disclosure,
- which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step,
- provided the making available to the public occurred prior to the international filing date.

■ PCT Minimum Documentation (Rule 34)

International Search Report (ISR) (Rules 42 and 43)

■ Contains:

- IPC (International Patent Classification) symbols
- indications of the technical areas searched
- indications relating to any finding of lack of unity
- a list of the relevant prior art documents
- indications relating to any finding that a meaningful search could not be carried out in respect of certain (but not all) claims

■ Time limit to establish ISR and written opinion of the ISA:

- 3 months from the date of receipt of the search copy by the ISA (usually within approximately 16 months from the priority date if priority is claimed); or
- 9 months from the priority date, whichever time limit expires later

International Search Report (ISR)

PATENT COOPERATION TREATY		
PCT		
INTERNATIONAL SEARCH REPORT		
(PCT Article 18 and Rules 43 and 44)		
Applicant's or agent's file reference P08017	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/EP2009/060890	International filing date (day/month/year) 24/08/2009	(Earliest) Priority Date (day/month/year) 25/08/2008
Applicant RATIOPHARM GMBH		
<p>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.</p> <p>This international search report consists of a total of <u>4</u> sheets.</p> <p><input checked="" type="checkbox"/> It is also accompanied by a copy of each prior art document cited in this report.</p>		
<p>1. Basis of the report</p> <p>a. With regard to the language, the international search was carried out on the basis of:</p> <p><input checked="" type="checkbox"/> the international application in the language in which it was filed</p> <p><input type="checkbox"/> 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))</p> <p>b. <input type="checkbox"/> 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)).</p> <p>c. <input type="checkbox"/> With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.</p> <p>2. <input type="checkbox"/> Certain claims were found unsearchable (See Box No. II)</p> <p>3. <input type="checkbox"/> Unity of invention is lacking (see Box No III)</p> <p>4. With regard to the title,</p> <p><input checked="" type="checkbox"/> the text is approved as submitted by the applicant</p> <p><input type="checkbox"/> the text has been established by this Authority to read as follows:</p> <p>5. With regard to the abstract,</p> <p><input checked="" type="checkbox"/> the text is approved as submitted by the applicant</p> <p><input type="checkbox"/> the text has been established, according to Rule 38.2(b), 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</p> <p>6. With regard to the drawings,</p> <p>a. the figure of the drawings to be published with the abstract is Figure No. _____</p> <p><input type="checkbox"/> as suggested by the applicant.</p> <p><input type="checkbox"/> as selected by this Authority, because the applicant failed to suggest a figure</p> <p><input type="checkbox"/> as selected by this Authority, because this figure better characterizes the invention</p> <p>b. <input checked="" type="checkbox"/> none of the figures is to be published with the abstract</p>		

Form PCT/ISA/210 (first sheet) (April 2007)

International Search Report (ISR)

C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2007/143483 A (SMITHKLINE BEECHAM CORP [US]; WHITEHEAD BONNIE F [US]; HO PETER T C [U] 13 December 2007 (2007-12-13) page 8, paragraph 3; table 1	1-9
A	WO 2006/113649 A (SMITHKLINE BEECHAM CORK LTD [IE]; CARTER BARRY HOWARD [US]; CAMPBELL D) 26 October 2006 (2006-10-26) cited in the application the whole document	1-9

-/--

Further documents are listed in the continuation of Box C. See patent family annex.

Category : A

Relevant
Claims : 1-9

International Search Report (ISR)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2009/060890

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007143483	A	13-12-2007	NONE
WO 2006113649	A	26-10-2006	AR 054252 A1 13-06-2007 AU 2006236423 A1 26-10-2006 CA 2606207 A1 26-10-2006 CN 101203211 A 18-06-2008 EA 200702253 A1 28-04-2008 EP 1871347 A1 02-01-2008 JP 2008536931 T 11-09-2008 KR 20080005557 A 14-01-2008 US 2008206330 A1 28-08-2008
WO 2008067144	A	05-06-2008	EP 2088862 A2 19-08-2009

International Search Report (ISR)

Category : X, Y

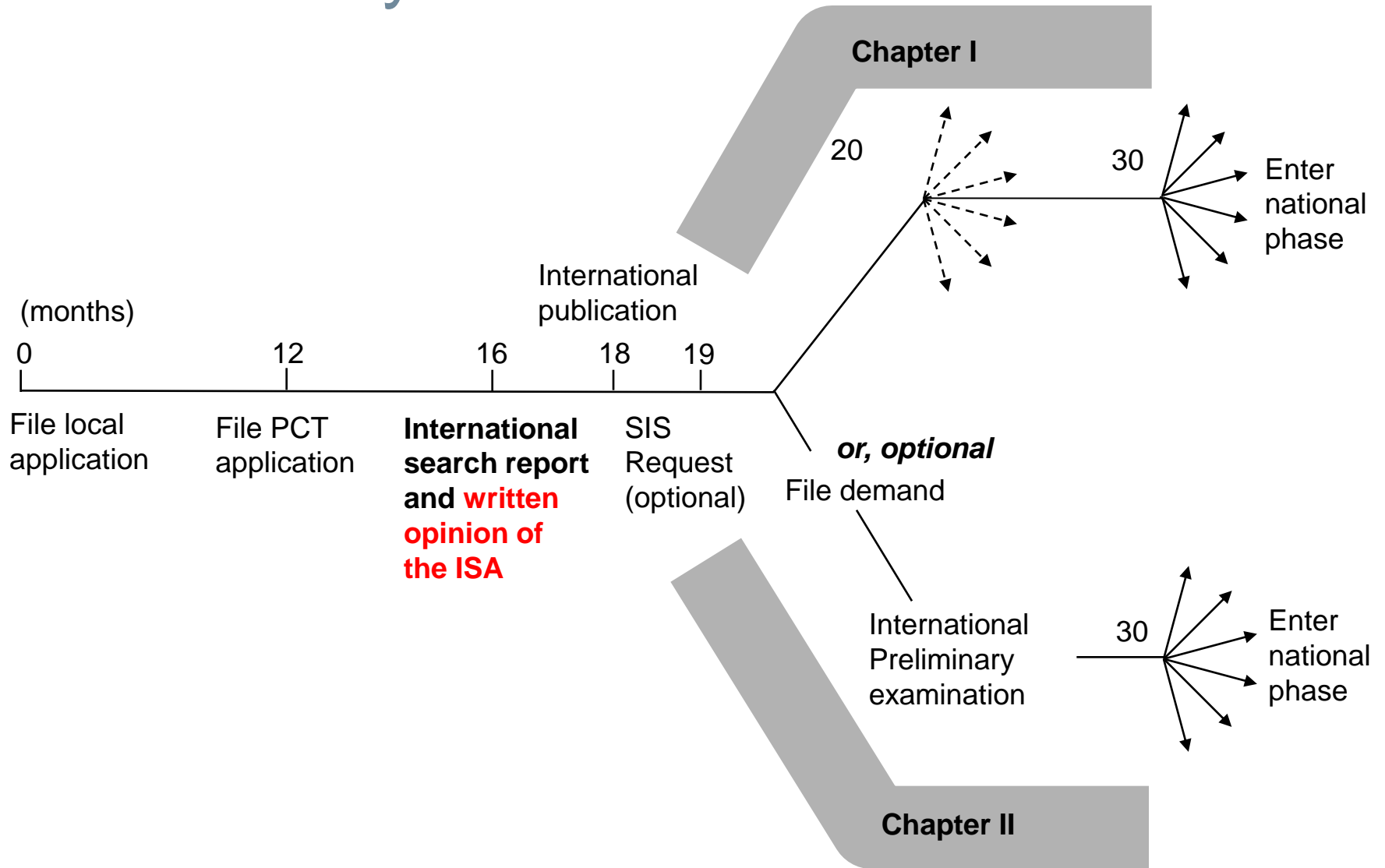
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/189715 A1 (MATTHEWS JOSEPH H [US] ET AL MATTHEWS III JOSEPH H [US] ET AL) 30 September 2004 (2004-09-30)	1-3,5-12
Y	paragraphs [0011], [0019], [0021], [0022], [0044], [0060] - [0062], [0068], [0074], [0076], [0077]; figures 1,9,13-16	4
Y	EP 2 053 850 A1 (VESTEL ELEKT SANAYI VE TICARET [TR]) 29 April 2009 (2009-04-29) column 9, line 51 - column 10, line 6; figures 4,5,9	4
X	US 6 552 738 B1 (LIN WALTER C [US] ET AL) 22 April 2003 (2003-04-22)	1-4,6-11
Y	column 1, line 22 - line 39; figures 1-4 column 1, line 67 - line 15 column 3, line 66 - column 5, line 59 ----- -/--	5,12

Relevant Claims

Further documents are listed in the continuation of Box C.

See patent family annex.

The PCT system



Written opinion of the ISA (Rule 43*bis*) (1)

- Initial preliminary non-binding opinion on:
 - novelty (not anticipated)
 - inventive step (not obvious)
 - industrial applicability
- A written opinion will be established for all international applications at the same time as the ISR
- The written opinion is sent to applicant and the International Bureau together with the ISR

Written opinion of the ISA (Rule 43bis) (2)

- The written opinion is made publicly available on PATENTSCOPE in its original language as of the date of publication of the international application
- No formal procedure for applicants to respond to written opinion of the ISA
- Possibility to submit informal comments to the International Bureau
 - They are made publicly available together with the written opinion in their original language
 - They are communicated to the DOs together with the IPRP (Chapter I) if and when it is sent
- Note: The IPRP Chapter I and its translation are established at 30 months from the priority date

Written opinion of the ISA

PATENT COOPERATION TREATY		
From the INTERNATIONAL SEARCHING AUTHORITY		
To: see form PCT/ISA220		PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)
		Date of mailing (day/month/year) see form PCT/ISA210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/EP2009/060890	International filing date (day/month/year) 24.08.2009	Priority date (day/month/year) 25.08.2008
International Patent Classification (IPC) or both national classification and IPC INV. A61K31/517		
Applicant RATIOPHARM GMBH		
<p>1. This opinion contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> 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</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> <p>2. FURTHER ACTION</p> <p>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.</p> <p>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/ISA220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA220.</p> <p>3. For further details, see notes to Form PCT/ISA220.</p>		
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/ISA210	Authorized Officer Zimmer, Barbara Telephone No. +49 89 2399-8600 

Written opinion of the ISA

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2009/060890

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>1-9</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-9</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-9</u>
	No: Claims	

2. Citations and explanations

see separate sheet

2. Novelty

Prior art document D1 discloses unit dosage forms comprising 0.5mg to 1000mg of lapatinib, which is below the amount claimed in the present application (p. 8, para. 3). Furthermore, a daily dose of 1250mg or 1500mg lapatinib is disclosed in D1 without, however, further specifying the amounts of active agent per unit dose (Table 1). Tablets comprising 250mg lapatinib are further known from D2 (ex. 1) and D3 is the package leaflet of Tyverb® 250mg, of which 5 tablets have to be administered per day.

Thus, in view of the cited prior art, the subject-matter of claims 1-9 seems to be novel (Art. 33(2) PCT).

Written opinion of the ISA

3. Inventive Step

D3, which is regarded as closest prior art, differs from the subject-matter of the present application in the amount of active agent per unit dose.

In view of the cited prior art, the technical problem of the present application seems to be the provision of an alternative dosage form of lapatinib, which is convenient to administer and which contains the whole daily lapatinib medication in a unit dose.

The provision of a unit dose comprising between 1200 and 1300mg lapatinib is not obvious in view of the cited prior art. As shown in the examples, the lapatinib formulations of the present application are even superior compared to the reference with regard to in-vitro parameters (fig. 1).

As a result, the subject-matter of claims 1-9 of the present application seems to involve an inventive step (Art. 33(3) PCT).

Written opinion of the ISA

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>4, 5, 9, 11, 12</u>
	No: Claims	<u>1-3, 6-8, 10</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-12</u>
Industrial applicability (IA)	Yes: Claims	<u>1-12</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Written opinion of the ISA

3 Novelty

Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of independent claims 1, 6 and 7 and dependent claims 2, 3, 8 and 10 is not new in the sense of Article 33(2) PCT, and the criteria of Article 33(1) PCT are therefore not met.

3.1 Claim 1: Document D1 discloses:

A method for displaying an on-screen display (Fig. 13-15) comprising the steps of:

determining at least one display parameter (paragraph [0022]: "...the various applications present a GUI tailored for control via a limited input device from a distance) of an on-screen display (paragraph [0022]: GUI; Fig. 13-15: 1302, 1402, 1502) based upon the type (paragraph [0021]: "...to switch between the first and second graphical user interface modes based on the input device used to control the operating system"; paragraph [0076]; Fig. 16) of user interface device (Fig. 1: 40, 42, 55; paragraph [0044]) used;

displaying said on-screen display according to said determined at least one display parameter (paragraphs [0022], [0062], [0077]).

3.2 Claim 6 is directed to a computer program product for carrying out the method of claim 1 and is therefore equally anticipated by document D1

Written opinion of the ISA

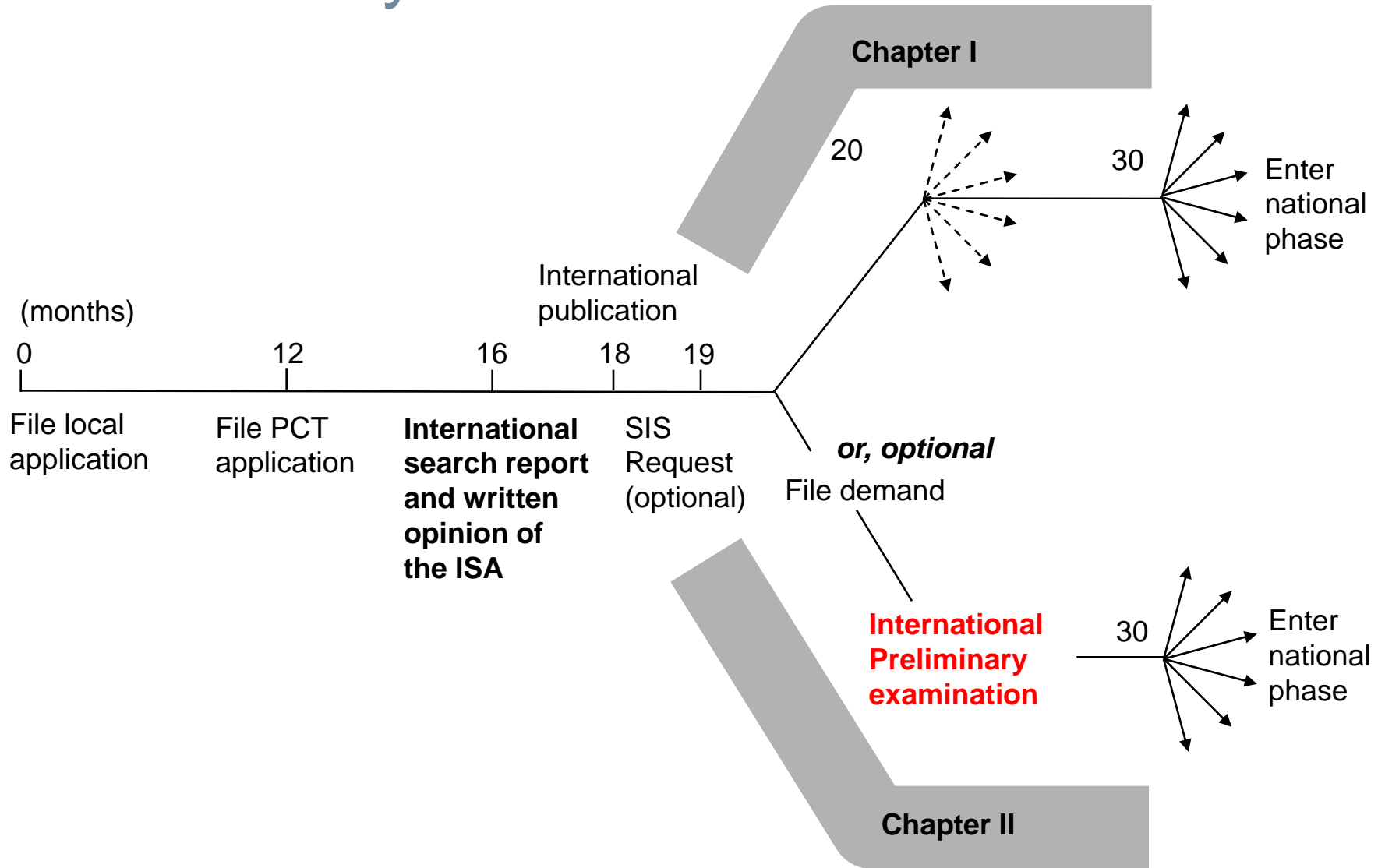
4 Inventive Step

Furthermore, the subject-matter of dependent claims 4, 5, 9, 11 and 12 does not involve an inventive step in the sense of Article 33(3) PCT, and the criteria of Article 33(1) PCT are therefore not met. Document D1 is considered to represent the closest prior art to the subject-matter of these claims.

4.1 Claim 4: Document D1 does not disclose determining the dimension of the on-screen display based on the distance between the remote control device and display of said on-screen display. Nevertheless, this practice is known from e.g. document D2, and the skilled person would simply adopt such known practice with corresponding effect starting from D1 in order to achieve constantly good readability of the OSD when the distance of the user from the display device is variable.

4.2 Claims 5, 9, 12: Document D1 is not specific about the location of the "*local control device*". Nevertheless, the skilled person would choose as Monitor 47 in Fig. 1 of D1 among any known display devices, among which are display devices with built-in USB ports as well as touch-screens. Therefore displays with built-in touch-screens or with a mouse/keyboard connected to the display USB ports fully fall within the scope of the "*local control device located on said*

The PCT system



International preliminary examination (1)

- Results in the establishment by the IPEA of a non-binding opinion on
 - novelty (not anticipated) (Article 33(2) and Rule 64)
 - inventive step (not obvious) (Article 33(3) and Rule 65)
 - industrial applicability (Article 33(4))
- International preliminary examination provides an opportunity to make amendments and to address patentability issues raised by the ISA

International Preliminary Examination (2)

- Only claims relating to the invention(s) searched by the ISA will be examined by the IPEA (Rules 66.1(e) and 66.2(a)(vi))

The International Preliminary Report on Patentability (Chapter II)

PATENT COOPERATION TREATY		
PCT		
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)		
(PCT Article 36 and Rule 70)		
Applicant's or agent's file reference 1099 PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2007/000669	International filing date (day/month/year) 09-07-2007	Priority date (day/month/year) -
International Patent Classification (IPC) or national classification and IPC See Supplemental Box		
Applicant Flir Systems AB et al		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p style="margin-left: 20px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 20px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 28-01-2009	Date of completion of this report 19-10-2009	
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM	Authorized officer Alexander Lakic / MRO Telephone No. +46 8 782 25 00	
Facsimile No. +46 8 667 72 88 Form PCT/IPEA/409 (cover sheet) (January 2009)		

The International Preliminary Report on Patentability (Chapter II)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages 1-4, 6-14 as originally filed/furnished

pages* 5 received by this Authority on 09.02.2009

pages* _____ received by this Authority on _____

the claims:

nos. 3-5 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-2 received by this Authority on 09.02.2009

nos.* _____ received by this Authority on _____

the drawings:

sheets 1-4 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

The International Preliminary Report on Patentability (Chapter II)

Box No. V		Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement			
Novelty (N)	Claims	_____ 1-5 _____	YES
	Claims	_____	NO
Inventive step (IS)	Claims	_____ 1-5 _____	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	_____ 1-5 _____	YES
	Claims	_____	NO

The International Preliminary Report on Patentability (Chapter II)

Claims 1-5

"A means for selecting a device to be operated, which selects an external device corresponding to a physical address designated in a first CEC message when a device not compatible with CEC is included in the input path via which a second CEC message is transmitted," described in claim 1, is not mentioned in the above document, nor would a person skilled in the art having reference to the above document easily conceive of said means.

Accordingly, the novelty and inventive step of the invention as set forth in claims 1-5 are not denied by the above document.

Challenges for National Examination

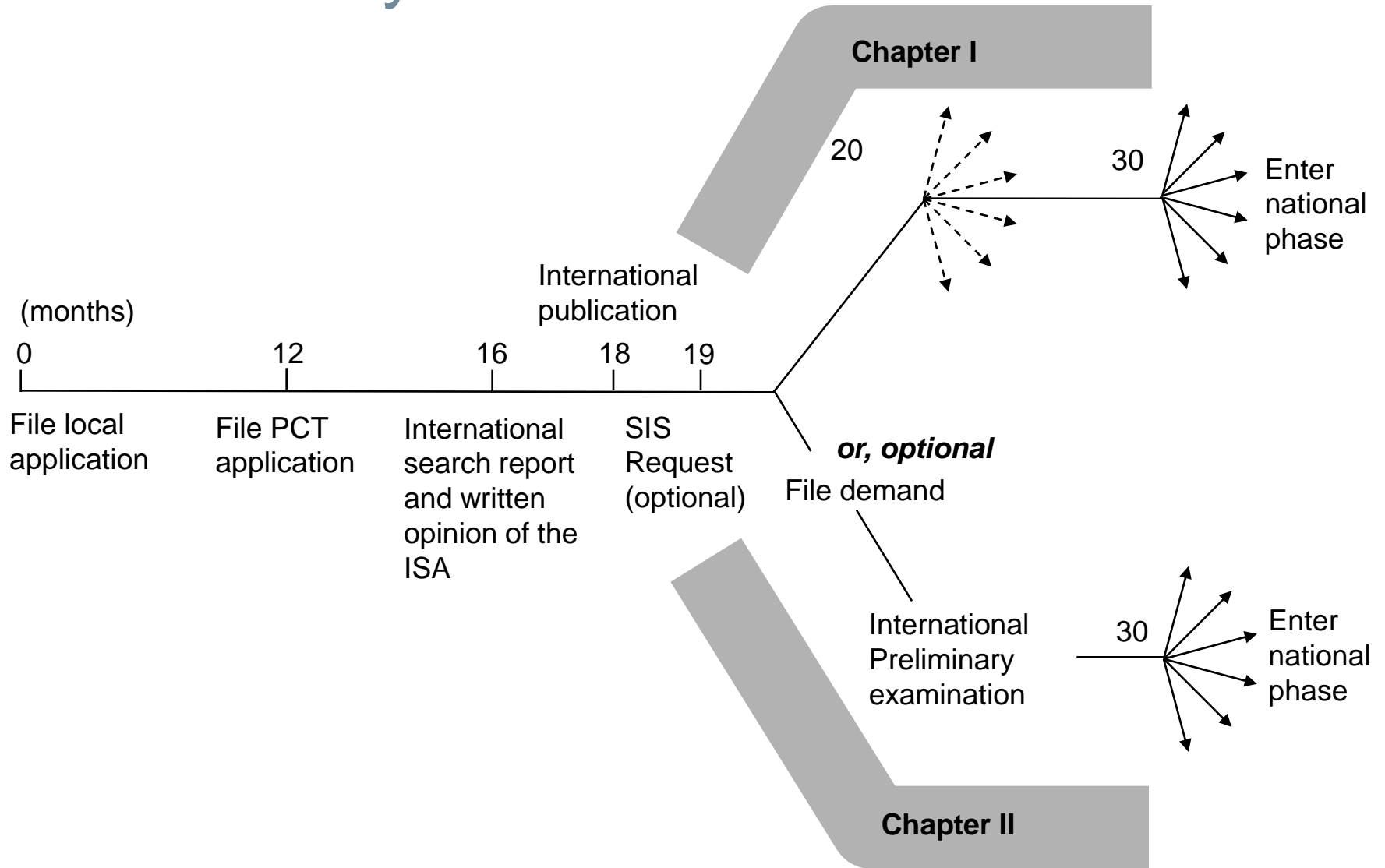
Amendments before / at the entry into National Phase

- Claim
- Description
- Drawings

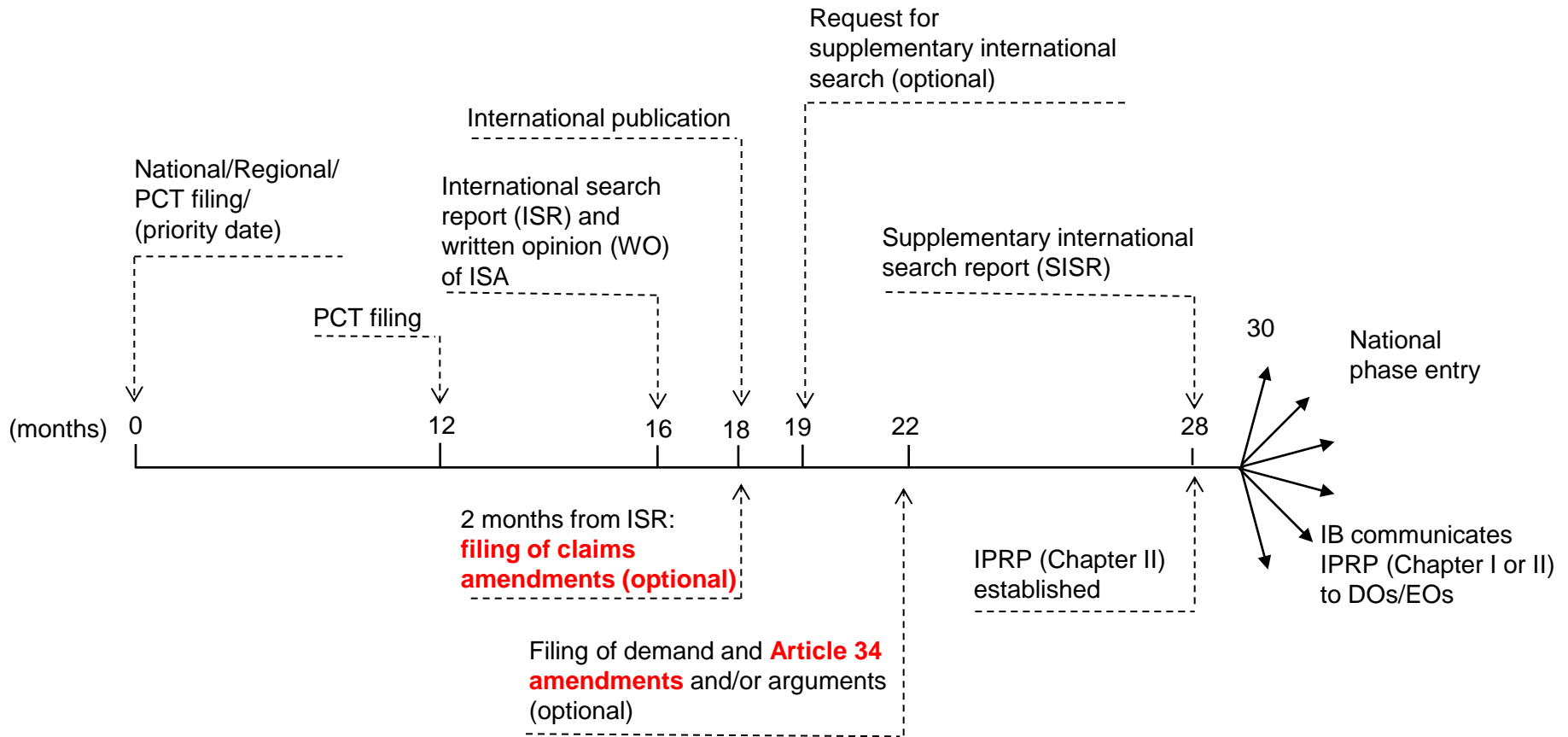
...

- When can applicants make amendments?

The PCT system



PCT TIMELINE



Before/After Amendments

Before Amendment



After Amendment

■ Invention composed of

- Element 1
- Element 2
- Element 3
- Element 4

■ Invention composed of

- Element 1
- Element 2
- Element 3
- Element 4
- Element 5**

Other Challenges

- Patentability Requirements (ISR, WOISA, IPRP Ch. II)
 - methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods
 - Computer programs
 - Business Method

- Insufficient Search Results (e.g. lack of unity)

Practical Approach for Better Quality

- Different size of the Office (could be different approach)
 - 1000 examiners or 10 examiners (for the whole technological fields)
 - Examination by its own examiners, outsourcing, temporary examiners ...

- Utilization of the results from other Offices
 - Wait for such results?