

Guidelines for Search and Examination at the European Patent Office as PCT Authority

November 2016

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General Part

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1. Preliminary remarks

As repeatedly requested by users since the removal of the part of the Guidelines for Examination in the EPO ("EP Guidelines") that dealt with the EPO as PCT Authority, the EPO in the present Guidelines is publishing the specific procedures and substantive issues before the EPO as RO/(S)ISA/IPEA which until 2015 were contained mainly in internal instructions, in as far as they are relevant for the public.

These Guidelines can be used and referred to by examiners and formalities officers, as well as patent attorneys, in addition to the Euro-PCT Guide ("PCT procedure at the EPO, [International phase and entry into the European phase], Guide for applicants"), the PCT-RO (Receiving Office) Guidelines and the PCT ISPE (International Search and Preliminary Examination) Guidelines. They are complementary to, but not a substitute for, the ISPE and RO Guidelines, as well as the PCT Applicant's Guide ("WIPO PCT Guide"), all published by WIPO. They will exist in parallel with the Euro-PCT Guide which, as before, has the status of a Notice from the EPO.

Their full name is "Guidelines for Search and Examination at the European Patent Office as PCT Authority", or "PCT-EPO Guidelines" for short, and throughout these Guidelines they are referred to as "GL/PCT-EPO".

The PCT-EPO Guidelines are published as a standalone document in electronic format only, and will be revised on a yearly basis in autumn at the same time as the EP Guidelines. The electronic publication includes not only the online version in HTML format, but also a printable file.

This second edition of the PCT-EPO Guidelines is intended to contain at least those parts of existing internal instructions for examiners and formalities officers which are considered appropriate for publication. It should therefore not be expected to be as complete as the EP Guidelines. The aim is to gradually expand the document with each revision cycle. The major change with respect to the first edition is the addition of $\underline{Part\ F}$.

Any indication from readers drawing attention to errors as well as suggestions for improvement is highly appreciated and may be sent by email to Directorate 5.2.2, European and International Legal Affairs, PCT, at international_pct_affairs@epo.org.

2. Explanatory notes

2.1 Overview

The PCT-EPO Guidelines follow the structure of the EP Guidelines (Chapters A-C, E, F, G and H, without D because there is no opposition, limitation or revocation under the PCT), and as far as possible the organisation within each chapter is similar to that of the EP Guidelines, adapted to the particularities of the PCT system.

Thus, these Guidelines comprise the following seven parts:

Part A: Guidelines for Formalities Examination;

Part B: Guidelines for Search;

Part C: Guidelines for Procedural Aspects in Chapter II;

Part E: Guidelines on General Procedural Matters;

Part F The International Application

Part G: Patentability

Part H: Amendments and Corrections

<u>Part A</u> deals with the procedures for formalities examination at the EPO in its capacity as RO, (S)ISA and IPEA. <u>Part B</u> deals with search matters. <u>Part C</u> relates to procedures to be followed in <u>Chapter II</u>. Substantive requirements are dealt with in <u>Parts G</u> and <u>H</u> (see below).

Part E deals with procedural matters relevant to several or all of the stages in procedure at the EPO as PCT Authority. Part F deals with the requirements which the application must fulfil other than patentability, in particular unity of invention (Rule 13), sufficiency of disclosure (Art. 5), clarity (Art. 6) and the right to priority (Art. 8). Part G deals with excluded subject-matter (Art. 17(2)(a)(i) and Rule 39; Art. 34(4)(a)(i) and Rule 67), novelty (Art. 33(2)), inventive step (Art. 33(3)) and industrial application (Art. 33(4)). Part H deals with the requirements relating to amendments and corrections. It relates in particular to the right to amend, the allowability of amendments and the correction of defects and errors.

Each Part of the Guidelines is divided into Chapters, each sub-divided into numbered sections which are further sub-divided into paragraphs. Cross-references to other paragraphs are in the format GL/PCT-EPO, followed by the relevant letter of that Part, then the Chapter number (a Roman numeral) and then the section and paragraph numbers (thus, e.g. GL/PCT-EPO C-V, 4.2, would be used to refer to paragraph 4.2 of Chapter V of Part C of the PCT-EPO Guidelines). When referring to the Guidelines for Examination in the EPO, the same format is used, but with "GL/EPO" instead of "GL/PCT-EPO".

Marginal references to articles and rules without further identification relate to the Articles or Rules of the Patent Cooperation Treaty which provide authority for what is stated. It is believed that such references avoid the need for extensive quotation from the PCT itself. References to Articles or Rules of the European Patent Convention are followed by "EPC".

Art. 150(2) EPC

Marginal references to the ISPE Guidelines relate to the corresponding sections in those Guidelines and are an indication that the present Guidelines apply within the framework of the ISPE Guidelines, in conformity with the supplementary role of the EPC in the international phase.

Where the practice for EP and PCT applications is the same (e.g. for the assessment of novelty), cross-references are made to the EP Guidelines. Where the practices are only partially overlapping, the information is contained in full in the PCT-EPO Guidelines, in order to avoid possible confusion. Chapter 3, Annex I, provides an EPC-PCT equivalence table.

It goes without saying that whenever "his" or "he" is used in relation to examiner, applicant, inventor, etc., this should be understood as "her or his" and "she or he", respectively.

2.2 Applicability of the PCT-EPO Guidelines

These Guidelines are intended to cover normal occurrences. They should therefore be considered only as general instructions. The application of these Guidelines to individual international patent applications is the responsibility of the formalities and examining staff and they may depart from these instructions in exceptional cases. Nevertheless, as a general rule, parties can expect the EPO in its capacity as RO, (S)ISA or IPEA to act in accordance with these Guidelines until such time as they – or the relevant legal provisions – are amended. Notices concerning such amendments are published in the Official Journal of the EPO and on the EPO website. It should also be noted that these Guidelines do not constitute legal provisions.

2.3 Relationship between the PCT-EPO Guidelines and the ISPE Guidelines

It is explicitly pointed out that the PCT-EPO Guidelines are intended to be complementary to, but not a substitute for, the PCT ISPE¹ and RO Guidelines, as well as the PCT Applicant's Guide ("WIPO PCT Guide") and the Euro-PCT Guide² ("PCT procedure at the EPO, [International phase and entry into the European phase], Guide for applicants").

The ISPE Guidelines published by WIPO set out in detail the procedures and criteria to be followed by all International Searching and Preliminary Examining Authorities. Since practice varies amongst different authorities these Guidelines provide some degrees of freedom as to which procedure/criteria can be used. Such different criteria are listed in the ISPE Guidelines in appendices to the respective chapters or defined within a specific paragraph. Generally, the EPO will use the same criteria when searching and examining an international application as would have been used in the European procedure. This means that where the ISPE Guidelines are either silent or give no guidance on a particular topic, then the equivalent provisions of the EP Guidelines are applied *mutatis mutandis* to PCT search and preliminary examination. A list of policy options is provided in section 3.2 below, Annex II.

2.4 Further sources of information

Regularly updated general information on the EPO and specific information on the procedures before the EPO as receiving Office, International

¹ GL/ISPE and GL/RO: www.wipo.int/pct/en/texts/gdlines.html

^{2 &}lt;u>www.epo.org/applying/international/guide-for-applicants.html</u>

Authority (ISA, SISA and IPEA) and designated/elected Office under the PCT is provided in the Annexes to the WIPO PCT Guide³. Relevant information is also provided on the EPO website⁴ and in the EPO's Official Journal ("OJ"), which is published in electronic form only⁵.

Up-to-date news about the PCT is available on the WIPO website and also from the PCT Newsletter and the Official Notices (PCT Gazette), both published in electronic form by WIPO⁶.

Applicants desiring further information about the PCT procedure in the international phase are advised to consult the Administrative Instructions under the PCT ("AI")⁷, the PCT Receiving Office Guidelines ("GL/RO") and the PCT International Search and Preliminary Examination Guidelines ("ISPE Guidelines", "GL/ISPE"), all available on the WIPO website.

2.5. Abbreviations

In these Guidelines, the following abbreviations are used:

AAD	Arrangements for the automatic debiting procedure
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ADA Arrangements for deposit accounts

Al Administrative Instructions under the PCT

Art. Article

EPC European Patent Convention

EPO European Patent Office

ESOP European search opinion

GL/EPO Guidelines for Examination in the EPO

GL/ISPE PCT International Search and Preliminary

Examination Guidelines

GL/PCT-EPO Guidelines for Search and Examination at the EPO

as PCT Authority

GL/RO PCT Receiving Office Guidelines

IB International Bureau

IPE International preliminary examination

Official Notices (PCT Gazette): www.wipo.int/pct/en/official_notices/index.html

³ www.wipo.int/pct/en/appguide/index.jsp

⁴ www.epo.org

⁵ www.epo.org/law-practice/legal-texts/official-journal.html

⁶ PCT Newsletter: www.wipo.int/pct/en/newslett/

⁷ AI: www.wipo.int/pct/en/texts/index.html

IPEA International Preliminary Examining Authority

IPER International preliminary examination report

IPRP International preliminary report on patentability

ISA International Searching Authority

ISR International search report

OJ EPO Official Journal of the European Patent Office

PCT Patent Cooperation Treaty

PCT-CLAR Request for clarification before search

PPH Patent Prosecution Highway

RFees Rules relating to Fees

RO Receiving Office

SIS Supplementary international search

SISA Supplementary International Searching Authority

SISR Supplementary international search report

WIPO World Intellectual Property Organization

WO-ISA Written opinion of the International Searching

Authority

2.6. Forms used by the ISA, SISA or IPEA

The following forms are used by the EPO as (S)ISA or IPEA:

PCT/ISA/210 International search report

PCT/ISA/237 Written opinion under Chapter I

PCT/ISA/207 Request for clarification before search

PCT/IPEA/408 Written opinion under Chapter II

PCT/IPEA/409 International preliminary report on patentability by

the IPEA under Chapter II

PCT/IPEA/428 Consultation/informal communication with the

applicant

PCT/SISA/501	Supplementary international search report
PCT/ISA/206	Partial search report and invitation to pay additional search fees following lack of unity
PCT/ISA/210	Search report, including any objection to lack of unity
PCT/ISA/212	Notification by the ISA to the applicant of the decision on protest by the Review Panel or, where the protest fee has not been paid, to inform the applicant that the protest cannot be considered
PCT/IPEA/405	Communication from the IPEA of its objection to lack of unity and to invite the applicant to restrict the claims or pay additional preliminary examination fees
PCT/IPEA/420	Notification by the IPEA to the applicant of the decision on protest by the Review Panel or, where the protest fee has not been paid, to inform the applicant that the protest cannot be considered
PCT/SISA/503	Notification by the SISA to the applicant of the decision on protest by the Review Panel or, where the protest fee has not been paid, to inform the applicant that the protest cannot be considered

The forms can be found via the following link: www.wipo.int/pct/en/forms/

2.7 Publications

Since 1 January 2009, the following kind codes have been used for publication of a PCT application:

Code	Publication details
A1	International application published with ISR
A2	International application published without ISR
A2	International application published with declaration under Article 17(2)(a)
А3	Later publication of ISR with revised front page
A4	Later publication of amended claims and/or statement (Article 19) with revised front page
A8	International application republished with corrections to front page bibliographic data
A9	International application or ISR republished with corrections, alterations or supplements (see also WIPO

Standard ST.50)

3. Annexes

3.1 Annex I: EPC-PCT equivalence table

Articles

EPC	PCT
82	Rule 13.1
83	<u>5</u>
84	<u>6</u>
<u>87, 88</u>	<u>8</u>
Rule 137(2)	<u>19(1)</u> , <u>34(2)(b)</u> and <u>Rule 66.4</u>
No equivalent	<u>28(1)</u> , <u>41(1)</u>
128(1)	30 (unpublished applications not available for inspection)
128(4)	Rule 94 – designated and elected Offices may allow access to files of international applications (EPO as elected Office allows access to preliminary examination files after completion of the IPER, OJ EPO 7/2003, 382)
<u>53(c)</u>	Rules 39.1, 67.1
<u>53(a)</u>	Rule 9.1(i) (ii)
<u>54(3)</u>	Rules 64.3, 70.10
<u>55</u>	Art. 27(5) (6), Rule 4.17(v), Rule 51bis.1(a)(v)
<u>54(1)</u>	<u>33(2)</u>
<u>54(2)</u>	Rule 64
<u>56</u>	<u>33(3)</u>
<u>57</u>	<u>33(4)</u>
<u>67(1)</u> , <u>(2)</u>	<u>29(1)</u>
<u>67(3)</u>	<u>29(2)</u>
<u>69</u>	<u>29(1)</u> , <u>(2)</u>

123(2)	19(2), 34(2)(b)
53(b)	Rule 39.1(ii), Rule 67.1(ii)
<u>76</u>	-
RULES	
EPC	PCT
42(1)(a)-(f)	5.1(a)(i)-(vi)
42(2)	<u>5.1(b)</u>
43(5)	<u>6.1(a)</u> , <u>(b)</u>
<u>43(6)</u>	<u>6.2(a)</u>
43(7)	6.2(b)
<u>43(1)</u>	<u>6.3(a)</u>
43(1)(a), (b)	6.3(b)(i),(ii)
43(4)	6.4(a) (part), (b), (c)
-	7 (some EPC member states require drawings for utility models – Art. 7(2)(ii) and Rule 7)
48	9.1(i), (ii), (iii), (iv)
<u>49(11)</u>	10.2
49(10)	10.1(a), (b), (d), (e)
<u>49(9)</u>	11.10
46(2)(j)	11.11
46(2)(i)	11.13(l), (m)
Art. 82	<u>13.1</u>
44(1)	13.2
44(2)	13.3
43(5)	<u>13.4</u>

13*bis*

30-34

<u>Art. 54(2)</u>	64.2 (prior use), 33.1(a), (b), (c), except that there is no provision for purely oral disclosure
Art. 54(3)	64.3, 70.10 (intermediate/conflicting documents)
- (derives from practice)	<u>65.1</u>
<u>Art. 89</u>	64.1(b)
137(3)	Art. 34(2)(b), 66.3(a), 66.4, 66.4bis
Art. 52(2), (4), 53(c)	<u>39.1, 67.1</u>

3.2 Annex II: Criteria chosen by the EPO as ISA/IPEA on specific points in the ISPE Guidelines

In a number of cases the ISPE Guidelines leave ISAs/IPEAs the choice between alternative guidelines upon which each ISA/IPEA may rely as appropriate.

The options are set out in the appendices to the chapters of the ISPE Guidelines mentioned below. The paragraph number (e.g. Point A5.16) refers to the relevant paragraph in the chapter concerned (in this case Chapter 5, point 16).

Option [1] applies

The EPO as ISA/IPEA has chosen the options listed below.

References to prior art

Appendix to Chapter 4

Point A4.05

	•			
Appendix to Chapter 5				
Point <u>A5.16</u>	Multiple dependent claims	Option [2] applies		
Point <u>A5.20</u>	Interpretation of claims	Option [2] applies		
Point <u>A5.21</u>	The EPO applies the first sentence concerning "use" claims			
Point <u>A5.26</u>	Product-by-process claims	Option [1] applies		
Point <u>A5.42</u>	Conciseness	Option [2] applies		

Appendix to Chapter 9

Point A9.07 Excluded subject matter Option [2] applies

Point A9.15 Programs for computers Option [2] applies

Appendix to Chapter 12

Point A12.02 Novelty: effective date Option [1] applies

Appendix to Chapter 13

Point The EPO applies the problem-solution approach

A13.08.1

Appendix to Chapter 14

Point The EPO applies the criterion of industrial

14.01[2] applicability

Appendix to Chapter 20

Point A20.21 Disclaimer Option [2] applies

PCT – Part A

Guidelines for Formalities Examination

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Chapter I – Introduction

<u>Part A</u> of the Guidelines for Search and Examination at the EPO as PCT Authority contains information concerning fees which is already present in the Guidelines for Examination in the European Patent Office, <u>Part A</u>, in as far as it specifically relates to international applications.

Further information on special aspects of formalities examination for international applications at the EPO will be added in subsequent revision cycles.

For additional information, reference is made to the Euro-PCT Guide ("PCT procedure at the EPO, Guide for applicants", 8th edition).

Chapter II - Fees

1. General

Guidance for the payment of fees, costs and prices, with information about international applications, the amounts of the principal fees for international applications and an extract from the <u>Rules relating to Fees</u>, is published at regular intervals in the Official Journal. Information relating to fees and methods of payment, including the EPO bank account for payments in euro, can also be found on the EPO website (<u>www.epo.org</u>) under: Applying for a patent/Forms and fees/Making payments. Applicants are also recommended to consult the latest information available on the WIPO website.

2. Amounts of fees

See Euro-PCT Guide, points 173-176.

3. Methods of payment

All fees which are to be paid to the EPO must be paid in euros by payment or transfer to a bank account held by the EPO. For persons having a deposit account with the EPO, payment may be made by debit order for the fees due.

Payment by cheque delivered or sent directly to the EPO was abolished with effect from 1 April 2008.

OJ EPO 2007, 533 OJ EPO 2007, 626

See also Euro-PCT Guide, points 177-179.

3.1 Deposit accounts

Debiting of deposit accounts in principle occurs on the basis of a debit order signed by the account holder. A debit order may be filed using the EPO Online Filing software, the new online filing (CMS) or the Online Fee Payment service. It may also be filed on paper, by fax or via web-form filing, in which case the use of Form PCT/RO/101 or Form PCT/IPEA/401 is mandatory. To avoid the risk of payment being debited twice where a debit order is sent by fax, the original should not be filed subsequently (see point 6.2 of the Arrangements for deposit accounts, <u>Supplementary publication 3, OJ EPO 2015, 8</u>).

Point 6.2 ADA

The Arrangements for deposit accounts (hereinafter abbreviated to "ADA") and their annexes are published as <u>Supplementary publication 3</u>, <u>OJ EPO 2015</u>.

3.2 Automatic debiting procedure

A deposit account may also be debited on the basis of an automatic debit order signed by or on behalf of the account holder (automatic debiting procedure).

Point 8 ADA

As from 1 April 2015 automatic debiting is allowed for international applications in proceedings before the EPO as receiving Office, ISA or

Supplementary publication 3, OJ EPO 2015, 17 IPEA. For the type of fees covered, see points 3 and 4 of Annex A.1 to the ADA

The Arrangements for the automatic debiting procedure (abbreviated to "AAD") plus explanatory notes are published as Annexes A.1 and A.2 to the ADA in <u>Supplementary publication 3</u>, <u>OJ EPO 2015</u>, <u>17</u> and <u>35</u>. The AAD can also be found on the EPO website (<u>www.epo.org</u>) under: Applying for a patent/Forms and fees/Making payments.

See also Euro-PCT Guide, points 177-179.

4. Reduction of fees

4.1 Reduction of the international filing fee

See Euro-PCT Guide, points 180-186.

4.2 Reduction of the fees for the international search and international preliminary examination of an international application

OJ EPO 2008, 521

The fees for the international search and preliminary examination of an international application are reduced by 75% if the application is filed by a natural person who is a national and a resident of a state which is not an EPC Contracting State and which, on the date of filing of the application or of the demand, is listed as a low-income or lower-middle-income economy by the World Bank.

5. Refund of fees

5.1 Refund of the international search fee

Rule 16.2 and Rule 16.3 PCT Rule 41 OJ EPO 2010, 304 OJ EPO 2014, A30 OJ EPO 2009, 99 The international search fee will be refunded in the cases specified in <u>Rules 16.2</u>, 16.3 and 41 and in Annex C of the Agreement between the European Patent Organisation and the International Bureau of the World Intellectual Property Organization (WIPO) under the PCT (see OJ EPO 2010, 304). Following amendment of the provisions set out in Annex C, Part II(3), of the above-mentioned agreement, any refund of the international search fee paid for an international application will be granted to the extent set out in the Decision of the President of the EPO dated 21 February 2014, <u>OJ EPO 2014</u>, <u>A30</u>, for international applications for which the international search report is completed on or after 1 July 2014. Details of the criteria for the refund of international search fees are given in the Notice from the EPO dated 9 January 2009, OJ EPO 2009, 99.

5.2 Refund of the international preliminary examination fee

OJ EPO 2001, 539

For international applications filed on or after 1 January 2004 the EPO has discontinued the rationalised international preliminary examination procedure. Consequently, no request for "detailed" examination will be required, and the fee refund for the rationalised procedure is no longer available.

6. Late payment of fees

See Euro-PCT Guide, points 187-189.

PCT – Part B

Guidelines for Search

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Chapter I – Introduction

1. Purpose of Part B

<u>Part B</u> is drafted for and applies to searches and written opinions established by the EPO as ISA or SISA in the context of <u>Chapter I of the Patent Cooperation Treaty</u> (PCT).

2. The examiner

The examiner appointed to carry out the search and establish the written opinion normally works on his own; at the discretion of the director an Examining Division can be appointed.

GL/ISPE 15.08-15.09

2.1 Consultation with other examiners

Section B-I, 2.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

2.2 Search Division consisting of more than one examiner

Section B-I, 2.2, in the Guidelines for Examination in the EPO applies *GL/ISPE 15.08* mutatis mutandis.

Chapter II - General

1. International search and written opinion under Chapter I

The procedure through which a PCT application proceeds from the filing of the application to the conclusion of the international phase comprises the international search and written opinion under <u>Chapter I</u>, which is mandatory for applicants, and the international preliminary examination under Chapter II, which is optional.

Art. 15 Art. 33

The objective of the international search is to discover the prior art which is relevant for the purpose of determining whether, and if so to what extent, the claimed invention to which the international application relates is or is not novel and does or does not involve an inventive step. The result of the search is communicated to the applicant in the form of an international search report. In some cases the International Searching Authority is not required to establish a search for some or all of the claimed subject-matter, e.g. because more than one invention is claimed or the application covers excluded subject-matter.

Art. 17 Rule 43 GL/ISPE 15 and 16

In its capacity as an International Searching Authority, the EPO is empowered not only to carry out the international search but also to formulate a preliminary and non-binding opinion on whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable When appropriate, an opinion will also be given on added subject-matter, unity, insufficient disclosure and clarity or support issues, as well as formal defects.

Rule 43bis GL/ISPE 17

This opinion is sent to the applicant in the form of a written opinion of the International Searching Authority (WO-ISA) together with the search report. If no international preliminary examination report is to be established because the applicant did not file a demand for preliminary examination, or the demand has been withdrawn, the International Bureau will prepare a report, entitled "international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)" having the same contents as the written opinion. Even if the applicant filed any amendments under Article 19, the amendments will not be taken into consideration in the international preliminary report on patentability (PCT Chapter I).

Rule 44bis GL/ISPE 2.18

The written opinion (and any informal comments filed by the applicant) will be made available to the public by the International Bureau at the same time as the international publication.

Art. 21(3) Rule 48.2 GL/ISPE 2.17

The EPO is an International Searching and Preliminary Examining Authority for the vast majority of PCT contracting states. All applications are treated in the same manner irrespective of their country of origin.

Art. 16, 32 Rule 35, 59 GL/ISPE 1.13-1.14

Although the PCT procedure differs in some procedural and formal aspects from the European procedure, the criteria for search and examination with respect to novelty, inventive step, industrial applicability, unity, non-patentable subject-matter or exclusions, insufficient disclosure and clarity

are in principle the same. This means that search and examination under the PCT is carried out in the same way and applying the same quality standard as for a European application in so far as the same requirements are examined.

There is no difference between an international and a European search, either in respect of the method and thoroughness of the search or in respect of the sources of prior art searched.

2. Objective of the search

Art. 15 Rule 33 GL/ISPE 15.01 The objective of the international search is to discover the prior art which is relevant for the purpose of determining novelty and inventive step. The international search as such, thus, does not differ from a European search.

3. Search documentation

Rule 34 GL/ISPE 15.45-15.51 Section B-II, 3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

4. Search report

Art. 18 Rule 43 GL/ISPE 16.01 An international search report is prepared containing the results of the search, in particular by identifying the documents constituting the relevant state of the art (see GL/PCT-EPO B-X, 9).

Rule 43bis.1

The search report is accompanied by a written opinion of the International Searching Authority (see GL/PCT-EPO B-XI).

5. Time limit

Rule 42.1, 43bis.1 GL/ISPE 2.13, 16.05 The time limit for establishing the international search report and the WO-ISA is three months from the receipt of the search copy by the ISA or nine months from the priority date, whichever occurs later. In practice this means that the search and the written opinion should be established no later than 16 months from the priority date.

Chapter III - Characteristics of the search

1. Scope of the search

1.1 Completeness of the search

The scope of the international search is defined in <u>Art. 15(4)</u>, stipulating that the International Searching Authority must endeavour to discover as much of the relevant prior art as its facilities permit and must, in any case, consult the documentation specified in the PCT Regulations (<u>Rule 34</u>). It follows from this definition ("as its facilities permit") that the scope of an international search is equivalent to that of a European search. International and European searches are thus fully identical in scope.

Art. 15(4) Rule 34

See also ISPE Guidelines 15.18 and 15.20.

1.2 Effectiveness and efficiency of the search

Section B-III, 2.2, in the Guidelines for Examination in the EPO applies mutatis mutandis.

GL/ISPE 15.46-15.47

1.3 Search in analogous fields

Section B-III, 2.3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

Rule 33.2(b), (c) GL/ISPE 15.48-15.51

1.4 Search on the internet

Section B-III, 2.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

GL/ISPE 15.56-15.59

Concerning the dating of internet citations, see GL/PCT-EPO G-IV, 6.4.

2. The subject of the search

2.1 Basis for the search

See ISPE Guidelines 15.21 and 15.23.

Art. 15(3) Rule 33.3(a)

2.2 Interpretation of claims

Section B-III, 3.2, in the Guidelines for Examination in the EPO applies mutatis mutandis.

GL/ISPE 15.22

2.2.1 Claims with explicit references to the description or drawings

Although explicit references in the claims to features elucidated in the description or in the drawings are only permissible where "absolutely necessary" (cf. <u>GL/PCT-EPO F-IV, 4.17</u>), if claims contain such references, the examiner should strive to search these technical features as long as they are unambiguously defined by specific parts of the description.

Rule 6.2(a) GL/ISPE 5.10, GL/ISPE 16.30

However, where the reference does not clearly identify which subject-matter of the description and/or drawings is to be considered as included in the claim, the examiner may informally contact the applicant for clarification before the search is carried out (see <u>GL/PCT-EPO B-VIII, 3.3</u>). In the special case of "omnibus claims" (e.g. a claim reading "The invention

substantially as herein described"), no request for informal clarification should be issued, and subsequently the search report will be designated as complete.

The procedure above should be followed regardless of whether or not the reference to the drawings and/or the description is allowable according to Rule 6.2(a).

Where the reference does not appear to be justified, the examiner should raise an objection in the written opinion.

2.3 Amended claims or incorporated missing parts

2.3.1 General considerations

Art. 19 Rule 91.1 GL/ISPE 15.10, 15.23 Since there is no right to amend the application until after the international search has been established, the international search must be carried out on the basis of the search copy of the application as transmitted to the EPO as ISA by the RO, except that obvious mistakes or formal matters which are contrary to the PCT and are called to the applicant's attention by the RO may be corrected (see also <u>GL/PCT-EPO H-IV</u>).

2.3.2 Request for rectification of obvious mistakes (Rule 91)

Rule 91

An applicant can request authorisation to rectify obvious mistakes in the international application (see <u>GL/PCT-EPO H-IV, 2</u>). The examiner (if the request relates to the description, claims or drawings) will have to assess whether such a request can be authorised according to the criteria set out in <u>Rule 91</u> – see <u>GL/ISPE 8.07-8.08</u>. If a RO has erroneously authorised such rectification, this may affect the search (see <u>GL/PCT-EPO H-IV, 2.1</u>).

Art. 19 GL/ISPE 15.10 If the changes requested by the applicant before the receipt of the ISR are not corrections, but rather amendments, the examiner must refuse them, because there is no right to amend the application until after the international search report has been established. This applies even if the applicant refers to them as corrections and even if they would be allowable amendments not adding subject-matter to the application as originally filed. For example, reformulation of claims, deletion of technical terms, deletion or limitation of claims and the taking of subject-matter from the description into the claims must all be refused at this stage regardless of whether or not they might be allowable, since they are not corrections, but rather substantive amendments.

2.3.3 Incorporating missing parts completely contained in the priority document

Rule 20.6

An applicant that has omitted to file parts of the application may still furnish them at a later date without affecting the international filing date, subject to the requirements of Rules 4.18 and 20.6(a) and provided the missing part(s) were completely contained in the priority document. The examiner checks whether the RO's assessment of the "completely contained" criterion was correct (see GL/PCT-EPO H-II, 2.2.2). If a RO has erroneously considered that the missing part(s) were completely contained in the priority document, the search should be extended to include

documents which would be relevant if the application were to be redated (such documents can be cited as "L" in the ISR).

2.4 Anticipation of amendments to claims

Section B-III, 3.5, in the Guidelines for Examination in the EPO applies mutatis mutandis.

Rule 33.3(b) GL/ISPE 15.25

2.5 Broad claims

Section B-III, 3.6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

GL/ISPE 15.26

2.6 Independent and dependent claims

Section B-III, 3.7, in the Guidelines for Examination in the EPO apply mutatis mutandis.

GL/ISPE 15.27

2.7 Search on dependent claims

Section B-III, 3.8, in the Guidelines for Examination in the EPO applies *mutatis mutandis*. See also GL/PCT-EPO F-IV, 3.3.

GL/ISPE 15.28

2.8 Combination of elements in a claim

Section B-III, 3.9, in the Guidelines for Examination in the EPO applies mutatis mutandis.

GL/ISPE 15.31

2.9 Different categories

Section B-III, 3.10, in the Guidelines for Examination in the EPO applies mutatis mutandis.

GL/ISPE 15.32

2.10 Subject-matter excluded from search

The examiner may exclude certain subject-matter from his search. These exclusions may result from the international application including subject-matter which the EPO as ISA is not required to deal with (see <u>GL/PCT-EPO B-VIII, 2</u>). They may also arise because the description, claims or drawings fail to meet a requirement, such as clarity or support of the claims by the description, to such an extent that no meaningful search can be carried out for all or some of the claims (see <u>GL/PCT-EPO B-VIII, 3</u>).

Art. 17(2)(a) Rule 39 GL/ISPE 15.33

2.11 Nucleotide and amino acid sequences

If, after an invitation from the EPO as ISA according to <u>Rule 13ter.1</u>, the applicant has not submitted the sequence listing in the required electronic form and text format and paid the late furnishing fee within the time limit set, the EPO as ISA will carry out the international search without the sequence listing to the extent that a meaningful search can be carried out (see also <u>GL/PCT-EPO B-VIII, 3.2</u>).

Rule 5.2, 13ter.1 OJ EPO 2007, Spec. ed. 3, C.2 OJ EPO 2011, 372 OJ EPO 2013, 542 GL/ISPE 9.39, GL/ISPE 15.12

2.12 Lack of unity

When the claims of the international application do not relate to one invention only, nor to a group of inventions so linked as to form a single general inventive concept, the applicant will normally be invited to pay additional search fees. If the applicant does not pay any additional search fees in response to the invitation, the international search will normally be

Art. 17(3)(a) GL/ISPE 15.24 restricted to those parts that relate to the invention, or so linked group of inventions, first mentioned in the claims. If additional fees have been paid within the prescribed time limit, those parts that relate to the inventions covered thereby are also searched. See also <u>GL/PCT-EPO B-VII</u>.

2.13 Technological background

GL/ISPE 15.30

Section B-III, 3.13, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Chapter IV – Search procedure and strategy

1. Analysis of the application prior to searching

1.1 Requests to take an earlier search into account

Applicants may request the ISA to take any earlier searches into account, including searches not carried out by the EPO.

Rules 4.12, 12bis and 41.1

It may happen that the PCT application to be searched by the EPO as ISA is a "doublure" of a previous application. A later filed application is considered as a doublure when (i) the search report for the first application is issued by the EPO, (ii) the earlier application is claimed as priority, (iii) this priority claim is valid, and (iv) the later search report can at least partly be based on a search report of the earlier application.

Where the EPO can base the ISR on an earlier search that it has performed on an application whose priority is validly claimed for the international application, the international search fee paid will be refunded in part or in full depending upon the extent to which the EPO benefits from that earlier search. No refund is made if priority has not been validly claimed.

Rules 4.12, 12bis, 16.3, 41.1 OJ EPO 2009, 99 OJ EPO 2014, A30

A request to take into account an earlier search not made by the EPO has no impact on the work of the examiner, who will do an independent full-scope international search. However, the documents cited in the earlier search report (which will be available in the file) might be useful. No refund is made for an earlier search that was not carried out by the EPO itself.

1.2 PCT Direct applications

Under PCT Direct, an applicant filing an international application claiming priority from an earlier national, European or international application already searched by the EPO (i.e. a "doublure"; see <u>GL/PCT-EPO B-IV</u>, 1.1) is able to react to any objections raised in the search opinion drawn up for the priority application. This simplifies the assessment of the international application and adds to the value of the international search report and written opinion established by the EPO.

OJ EPO 2015, A51

1.2.1 Requests for PCT Direct

Applicants may request to have their international application processed under PCT Direct by filing a letter ("PCT Direct letter") containing informal comments aimed at overcoming objections raised in the search opinion established by the EPO for the priority application. Such informal comments are to be understood as arguments regarding the patentability of the claims of the international application and also possibly as explanations regarding any modifications to the application documents, in particular to the claims, in comparison with the earlier application. PCT Direct letters do not form part of the international application.

Upon receipt of a PCT Direct letter, the international application will be processed under PCT Direct only where the following two requirements are met:

- (a) the informal comments are filed together with the international application with the receiving Office in the form specified in <u>GL/PCT-EPO B-IV, 1.2.2</u>, and
- (b) the international application claims priority of an earlier application searched by the EPO (European, national or international first filing).

1.2.2 Form of submissions

PCT Direct letters are to be presented as a separate document attached to the international application; they should be entitled "PCT Direct / informal comments" and clearly identify in the header the application number of the earlier application.

If the claims and/or the description of the international application differ from those of the earlier application, applicants should preferably submit a marked-up copy indicating the differences.

The PCT Direct letter and any marked-up copy of the claims and/or description are to be submitted as a single document in PDF format (not as ZIP) and indicated by checking Box IX of the PCT request form (check list, Form PCT/RO/101). In particular, the words "PCT Direct/informal comments" should be specified under point 11, "Other", for filings on paper and as a remark for filings in electronic form using the EPO online filing software or the EPO new online filing (CMS). For filings in electronic form using WIPO's ePCT portal, the PCT Direct letter and any marked-up copy of the claims and/or description are to be uploaded as "Other documents" by selecting the box "Applicant letter to ISA concerning earlier search ("PCT Direct")".

Informal comments filed under PCT Direct must be self-contained. This means that third parties must be able to fully understand these comments as they stand. If explicit references are made to the written opinion for the first filing, the latter should be annexed to the international application. The reason for this requirement is that the search report, the search opinion or any other submissions that are part of the file of the earlier application may not be publicly available.

1.2.3 Processing of PCT Direct letters

PCT Direct letters filed with the receiving Office will be transmitted to the EPO as International Searching Authority and to the International Bureau of WIPO together with the search copy and record copy, respectively.

At the EPO as International Searching Authority, the examiner performing the international search will take informal comments filed under PCT Direct into account when preparing the international search report and written opinion, provided that they meet the requirements (a) and (b) listed in GL/PCT-EPO B-IV. 1.2.1, and that they are in the form specified in

GL/PCT-EPO B-IV, 1.2.2. However, the examiner will not make explicit reference to the PCT Direct letter or its content.

In accordance with the PCT provisions on file inspection, PCT Direct letters will be available to the public on WIPO's PATENTSCOPE.

1.3 Third-party observations

For general information on third-party observations in the PCT phase, see PCT Al Part 8 GL/PCT-EPO E-I.

If the formalities officer forwards third-party observations to the examiner before a final report (ISR, SISR or IPER) is established, the examiner should consider them in the same way as he would in the European procedure (see GL/EPO E-V, 3). However, given that under the PCT thirdparty observations should refer to novelty or inventive step only, their relevance will in most cases depend on the relevance of the prior-art documents in support of them. Any document(s) provided to the examiner with the observations will either have been received from the IB or obtained by the formalities officer.

Third-party observations will normally not reach the examiner at the international search stage if the ISR is established and received by the IB on time, namely before publication of the application. However, this may happen when the international search is performed after an A2 publication.

If the third-party observations are relevant, the documents will be cited in the ISR and in section V of the WO-ISA. The examiner will take the thirdparty observations and the applicant's comments, if present, into account when drafting the WO-ISA.

GL/ISPE 15.68

If the third-party observations are not relevant or not sufficiently understandable, the documents will not be included in the ISR. The examiner will insert a comment in section V of the WO-ISA indicating that the third-party observations have been taken into account and found not to be relevant or that the third-party observations could not be taken into account, together with the reasons.

1.4 Documents cited in the application

See ISPE Guidelines 15.37.

2. Search strategy

2.1 Subject of the search; restrictions

See ISPE Guidelines 15.41.

2.2 Formulating a search strategy

Section B-IV, 2.2, in the Guidelines for Examination in the EPO applies GL/ISPE 15.47 mutatis mutandis.

2.3 Carrying out the search; types of documents

GL/ISPE 15.52

Section B-IV, 2.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

2.4 Reformulation of the subject of the search

GL/ISPE 15.53

Section B-IV, 2.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

2.5 Closest prior art and its effects on the search

Paragraphs 1 to 3 of section B-IV, 2.5, in the Guidelines for Examination in the EPO apply mutatis mutandis.

See also ISPE Guidelines 15.60.

2.6 End of search

GL/ISPE 15.61

Section B-IV, 2.6, in the Guidelines for Examination in the EPO applies mutatis mutandis.

3. Procedure after searching

3.1 Preparation of the search report

Art. 18 Rule 43.5 GL/ISPE 15.67, 15.69 and 15.72 Section B-IV, 3.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3.2 Amended international search report

It might happen that there was an error in the international search report and the applicant requests correction of that error. In such a case the examiner should consider issuing a corrected ISR (and possibly WO-ISA).

Further reasons for amending the international search report are indicated in ISPE Guidelines 15.74.

Chapter V – Preclassification (routing) and official classification of international patent applications

1. Definitions

Section B-V, 1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

2. Preclassification (routing and distribution)

Section B-V, 2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3. Incorrect preclassification

Section B-V, 3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

4. Official classification of the application

Section B-V, 4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 43.3 GL/ISPE 7.02-7.04 GL/ISPE 15.39

5. Amended classification of late-published search reports See ISPE Guidelines 7.05.

6. Classification when the scope of the invention is not clear

Section B-V, 6, in the Guidelines for Examination in the EPO applies GL/ISPE 7.06, 7.08 mutatis mutandis.

7. Classification in cases of a lack of unity of invention

Section B-V, 7, in the Guidelines for Examination in the EPO applies *GL/ISPE 7.07* mutatis mutandis.

8. Verification of official classification

Section B-V, 8, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

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Chapter VI – The state of the art at the search stage

1. General

The general considerations relating to the state of the art with regard to the determination of novelty and inventive step are set out in GL/PCT-EPO G-IV.

2. State of the art - oral disclosure, etc.

According to Rule 33.1(a) and (b), oral disclosure, use, exhibition, etc. are recognised as prior art only when this is substantiated by a written disclosure, contrary to Art. 54 EPC.

Rule 33.1(a), (b)

See also ISPE Guidelines 11.22 and 15.05.

Where a non-written disclosure occurs and both the non-written disclosure and the written account of it are published before the relevant date as defined in Rule 64.1(b), the examiner will cite the written account in the search report and give the date of the written disclosure on the search report. In this case, the written disclosure constitutes the prior art.

Rule 64.1(b)

If the written disclosure was made available to the public on or after the filing date of the international application concerned, the written disclosure will be cited in the international search report together with the date on which it was available, provided that the non-written disclosure was made available to the public prior to the filing date of the international application. The written opinion and the international preliminary examination report will draw attention to the non-written disclosure in Box No. VI (Certain documents cited).

Rule 64.2, 70.9

Where a non-written disclosure occurs but is not followed by any written account, it is not cited in the international search report, because it is not considered to be state of the art under the PCT. The examiner makes a note of this non-written disclosure and will reconsider its status if the application enters the regional phase before the EPO (see GL/EPO B-VI, 2).

3. Priority

Section B-VI, 3, in the Guidelines for Examination in the EPO applies GL/ISPE 11.02-11.03 mutatis mutandis.

4. Conflicting applications

4.1 Potentially conflicting European and international applications

Generally, where the international search is concluded less than eighteen months after the international filing date of the application, it will not be possible at the time of the search to make a complete search for potentially conflicting European and international applications. This search therefore has to be completed during the mandatory top-up search if a demand under Chapter II PCT has been made (see GL/PCT-EPO C-IV, 5) or alternatively at the examination stage by the Examining Division if the application enters the European phase before the EPO (see GL/EPO C-IV, 7.1).

4.2 National earlier rights

Section B-VI, 4.2, in the Guidelines for Examination in the EPO applies mutatis mutandis.

5. Date of reference for documents cited in the search report; filing and priority date

5.1 Verification of claimed priority date(s)

Section B-VI, 5.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

See also ISPE Guidelines 11.02-11.03.

5.2 Intermediate documents

Section B-VI, 5.2, in the Guidelines for Examination in the EPO applies mutatis mutandis.

5.3 Doubts as to the validity of the priority claim; extension of the search

Section B-VI, 5.3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

See also ISPE Guidelines 11.06.

5.4 Documents published after the filing date

Section B-VI, 5.4, in the Guidelines for Examination in the EPO applies mutatis mutandis.

See also ISPE Guidelines 11.11.

5.5 Non-prejudicial disclosures

Rule 51bis.1(v) Art. 55 EPC Potentially non-prejudicial disclosures should be cited in the international search report. Whether the disclosure falls within <u>Art. 55(1)(a)</u> or <u>(b) EPC</u> will be investigated by the Examining Division after the application has validly entered the European phase.

See also ISPE Guidelines 16.76.

5.6 Matters of doubt in the state of the art

Section B-VI, 5.6, in the Guidelines for Examination in the EPO applies mutatis mutandis.

See also ISPE Guidelines 11.23 and 15.64-15.65.

6. Contents of prior-art disclosures

6.1 General remark

Section B-VI, 6.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

6.2 Citation of documents corresponding to documents not available or not published in one of the official EPO languages

Section B-VI, 6.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

6.3 Conflict between abstract and source document

Section B-VI, 6.3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

6.4 Insufficient prior art disclosures

Section B-VI, 6.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

6.5 Incorrect compound records in online databases

Section B-VI, 6.5, in the Guidelines for Examination in the EPO applies mutatis mutandis.

7. Internet disclosures - technical journals

Section B-VI, 7, in the Guidelines for Examination in the EPO applies mutatis mutandis.

See also ISPE Guidelines 11.13.

Chapter VII - Unity of invention

1. General remarks

Unity is assessed in the same way in the PCT and European procedures. However, the consequences of a finding of lack of unity at the search and/or examination stages are different under the PCT, as are the actions to be taken by the examiner. In particular, the applicant may be asked to pay additional search and/or examination fees and he may do so under protest.

Furthermore, divisional applications are not allowed under the PCT.

2. Lack of unity at the search stage

If the lack of unity finding is raised at the search stage, a search is conducted for the invention first mentioned in the claims and the applicant is invited to pay additional search fees with Form PCT/ISA/206 (hereafter referred to as "Form 206"). On Form 206 the examiner must also give a complete and self-contained reasoning for the lack of unity. The applicant can then decide to:

Art. 17(3)(a) Rule 13, 40.1 GL/ISPE 10

- (i) not pay any further fees,
- (ii) pay some or all fees without protest or
- (iii) pay some or all fees under protest.

At the same time as preparing the invitation (Form 206) the examiner must complete the WO-ISA for the searched first invention. However, at this stage only the invitation to pay further fees (Form 206) is actually sent to the applicant.

In the case of a doublure (see <u>GL/PCT-EPO B-IV, 1.1)</u> where the earlier application also lacked unity, the applicant should be invited to pay additional fees even if all inventions were searched in the earlier application. The amount refunded will then be decided for each invention separately.

3. No request for payment of additional search fees

Exceptionally it might be chosen not to request the applicant to pay additional search fees, even if an objection as to lack of unity occurs. This could be the case when the additional search effort for the other invention(s) is minor. However, it must be borne in mind that the written opinion under <u>Chapter I</u> must be written for all inventions that were searched, without asking for extra examination fees. As a consequence, for consistency reasons the examiner should not ask for extra examination fees should a demand for international preliminary examination under <u>Chapter II</u> be filed (see <u>GL/PCT-EPO C-V, 3.3</u>). Thus, when deciding on whether to ask for additional search fees, the examination effort for the whole procedure must also be taken into account.

If an objection of lack of unity has been raised but it was exceptionally chosen not to request the applicant to pay additional search fees, the ISR is issued for all inventions, indicating that the application lacks unity and listing the different groups of inventions. The WO-ISA is completed for all searched inventions. In Section IV of the WO-ISA, the examiner indicates that the requirement of unity is not fulfilled and that all claims have been searched and examined and provides full reasons on the separate sheet.

4. Cascading non-unity

If additional search fees are paid in response to an invitation to do so and the additional search(es) reveal(s) a further lack of unity "a posteriori", no further invitation to pay further additional search fees is issued.

If the applicant pays (an) additional search fee(s), a search is carried out for the invention(s) for which the search fee(s) has/have been paid.

If the search reveals that one or more of these inventions also lack unity "a posteriori", only the first invention of each of the groups of inventions is searched.

The WO-ISA will be drafted for all the searched inventions. Section III must be modified to cover the inventions actually searched. Under Section IV, full reasons must be given for all the non-unity objections raised. Under Section V an opinion as to novelty, inventive step and industrial applicability must be given for all searched inventions.

Claims not searched during the international phase can be prosecuted during the regional phase before the EPO in accordance with <u>GL/EPO F-V</u>, <u>13.1</u>, as appropriate.

Example

A lack of unity objection is raised by the EPO acting as ISA, identifying four different inventions A, B, C and D. The first invention A is searched and the applicant is invited to pay further search fees for inventions B, C and D.

The applicant pays two further search fees for inventions B and C. During the additional search, B is found to lack unity "a posteriori" and is divided into the groups of inventions B1, B2 and B3.

In this case only B1 and C are searched, so in Section III of the WO-ISA the claims relating to inventions B2, B3 and D are indicated as not searched. In Section IV, full reasons must be given for why the claims of the application were divided into A, B, C and D and why B was further subdivided into B1, B2 and B3. Under Section V an opinion on patentability must be given for A, B1 and C.

Examination of the application in the European phase will be based on either A, B1 or C (see <u>GL/EPO F-V, 13.1(iii)</u>). For the claims relating to inventions B2, B3 and D, an invitation under <u>Rule 164(2) EPC</u> will be issued in accordance with <u>GL/EPO F-V, 13.1(iv)</u>.

5. Documents relevant only to other inventions

The provisions of section B-VII, 1.3, in the Guidelines for Examination in the EPO apply *mutatis mutandis*.

6. Reply from the applicant to the invitation to pay additional search fees

6.1 No payment of additional search fees

If, after an invitation to pay additional search fees, the applicant does not pay further fees, the file will not be returned to the examiner, but the final search report and the WO-ISA, which were already prepared by the examiner at the initial search stage, will be sent out by the formalities officer.

6.2 Payment of additional search fees without protest

If, after an invitation to pay additional search fees, the applicant has paid additional search fees without protest, a complete search will be carried out for the inventions for which search fees have been paid and the ISR will be issued for these inventions. The WO-ISA will be drafted for the claims for which search fees have been paid. Section IV is to be filled out, and Section III must be modified to the actual payment of fees.

6.3 Payment of additional search fees under protest

In reply to Form 206, the applicant may pay some or all of the additional fees under protest. If he does, then this triggers the protest procedure for determining whether the request for payment of the additional fees was justified (see also <u>GL/PCT-EPO B-VII. 7</u>).

Rule 40.2(c) GL/ISPE 10.66-10.69

If the applicant has paid additional search fees under protest and the Review Panel decided that the protest was fully or partly justified, the examiner will follow the decision of the Review Panel and will proceed to establish the ISR and WO-ISA for the inventions for which search fees have been paid. In the ISR the examiner will adapt the number of inventions and their definitions as well as the non-unity reasoning to be consistent with the decision of the review panel. In the WO-ISA, Section IV and the reasoning will be adapted to the decision of the Review Panel and Section III will be modified to the actual payment of fees. Under Section V an opinion as to novelty, inventive step and industrial applicability for all searched inventions will be given.

In the special situation where the protest was fully justified and where, as a consequence, the application is considered unitary, the examiner will follow the decision of the Review Panel and send a final ISR with no indication of non-unity. In Section IV of the WO-ISA the examiner will indicate that the requirement of unity of invention is complied with and that the search report has been established in respect of all parts of the application; no reasons need to be given on the separate sheet. Under Section V, an opinion as to novelty, inventive step and industrial applicability for all claims will be given.

If the applicant has paid additional search fees under protest and the Review Panel decided that the protest was not justified, the examiner will follow the decision of the Review Panel and proceed to establish the ISR and WO-ISA for the inventions for which search fees have been paid. In the ISR and the WO-ISA (Section IV) he will indicate that the requirement of unity is not complied with. Section III will be modified to the actual payment of fees, and under Section V an opinion as to novelty, inventive step and industrial applicability for all searched inventions will be given.

The final ISR and WO-ISA will be sent out together with the decision on protest (Form PCT/ISA/212) in order to ensure that both are consistent.

See also below (<u>GL/PCT-EPO B-VII, 7</u>), for the protest procedure and the work of the Review Panel.

7. Protest procedure

The procedure consists of a review within the ISA first by the formalities officer in charge of the file and then by a Review Panel.

7.1 Admissibility of the protest

Rule 40.2(c) and 40.2(e)

Before initiating the protest procedure the formal admissibility of the protest in the sense of <u>Rule 40.2(c)</u> (<u>Chapter I</u>) must be checked.

GL/ISPE 10.66-10.67 and 10.69 To be admissible the protest should satisfy the following requirements:

- (a) The applicant must have paid the prescribed protest fee (Rule 40.2(e)), and
- (b) The payment under protest must be accompanied by a reasoned statement, i.e. the reasoned statement should have been filed with the payment or at the latest within the time limit set in Form 206.

The reasoned statement must comply with <u>Rule 40.2(c)</u>; i.e. the applicant should argue why the international application complies with the requirement of unity of invention or why the amount of the required additional fee is excessive. In the protest the applicant should question the number of additional fees that he has been invited to pay, and not the amount of a single additional fee.

The payment of the protest fee and the presence of a reasoned statement are assessed by specially trained formalities officers. Any substantive analysis is made by the Review Panel when assessing the justification of the protest. If the applicant merely submits a statement of disagreement, the Review Panel will refer to the reasoning contained in the invitation to pay additional search fees (Form 206) when taking its decision.

7.2 Review Panel

GL/ISPE 10.68 OJ EPO 2015, A59 If the applicant pays the additional fees under protest and the protest is found admissible, the case is referred to the director to appoint a three-member Review Panel, which comprises the examiner in charge, an examiner as chairperson of the Review Panel and a further examiner. This Review Panel will, in case of entry into the European phase, constitute the

Examining Division. The names of the members of the Review Panel are made public on Form 212.

The Review Panel is appointed from the moment that the protest is found admissible. Its purpose is to determine, on the basis of the protest, whether the request for payment of additional fees by the examiner was justified on the basis of the reasoning given (see <u>W 11/93</u>). The review does not allow a re-evaluation to determine possible additional grounds for lack of unity (see W 9/07, Reasons 2.8).

The scope of the review is limited to those inventions for which additional fees have been paid. If the applicant's reasoning is not related to those inventions, the Review Panel will come to the conclusion that the protest is not or is only partially justified, depending on the case.

If the Review Panel determines that the protest is wholly justified, it will inform the applicant with Form 212 (Decision on Protest <u>Chapter I</u>). This also applies if the Review Panel's finding results in the application not lacking unity. It is not necessary to give any reasons unless the Review Panel decides that such reasoning would be beneficial. Furthermore, the Review Panel will order the reimbursement of all the additional fees and the protest fee. The search will be carried out and the written opinion established for the inventions for which the fees are paid (see GL/PCT-EPO B-VII, 6.3).

If the Review Panel considers that the protest is not justified at all, it will communicate this to the applicant with Form 212. Reasoning must be given indicating why the request for payment of the additional fees is upheld, including addressing the applicant's arguments to the extent reasonable. The search will be carried out and the written opinion established for the inventions for which the fees are paid (see GL/PCT-EPO B-VII, 6.3).

If the Review Panel considers that the protest is only partially justified, it will communicate this to the applicant with Form 212. Reasoning must be given indicating why the request for payment of the additional fees is partially upheld, including addressing the applicant's arguments to the extent reasonable. The search will be carried out and the written opinion established for the inventions for which the fees are paid (see <u>GL/PCT-EPO B-VII, 6.3</u>). The Review Panel will order the reimbursement of the corresponding additional fees but not the protest fee.

The formalities officer will send the decision of the Review Panel to the applicant and the IB. The decision on protest (Form 212) will be sent out together with the final ISR and WO-ISA in order to ensure that both are consistent.

8. Lack of unity and incomplete search

The procedures for dealing with cases which lack unity and where in addition a meaningful search is not possible are dealt with in <u>GL/PCT-EPO B-VIII, 3.6.</u>

GL/ISPE 10.70

Rule 13 Art. 17(2)(a)(ii) Art. 17(3)(a)

Chapter VIII – Subject-matter to be excluded from the search

1. General remarks

The aim of the EPO as ISA is to issue international search reports which are as complete as possible. Nevertheless, there are situations in which the search report and the written opinion cover only part of the subject-matter claimed, or in which no search report is issued. This may be either because the international application includes subject-matter which the ISA is not required to deal with (see <u>GL/PCT-EPO B-VIII, 2</u>) or else because the description, claims or drawings fail to meet a requirement, such as clarity or support of the claims by the description, to such an extent that no meaningful search can be made of all or some of the claims (see <u>GL/PCT-EPO B-VIII, 3</u>). Applications of the latter kind are often referred to as "complex applications".

GL/ISPE 9.01

The same approach is taken as for European applications.

In principle, a declaration of no search under Art. 17(2)(a)(ii) should remain an exception. Under the PCT, even if the applicant amends the claims to overcome the objection, an additional search is not possible. When a declaration of no search is issued, the search must be performed at the examination stage without requesting an additional fee if the international application enters the European phase before the EPO and if the objection leading to the declaration has been overcome (GL/EPO C-IV, 7.2). Therefore, at least some effort should be made to carry out a meaningful search of at least part of the claimed subject-matter.

Art. 17(2)(a)(ii) GL/ISPE 9.40

2. Subject-matter which the ISA is not required to search and examine

Art. 17(2)(a)(i) and Art. 34(4)(a)(i) together with Rules 39 and 67.1 are the equivalents of Art. 52(2), (3) and 53(b), (c) EPC concerning the exclusion from patentability of non-technical inventions, programs for computers, methods of doing business, medical methods and the exception to patentability for plant or animal varieties or essentially biological processes for the production of plants and animals, respectively. Since the PCT procedure does not lead to a grant, subject-matter which would be excluded from patentability under the EPC is identified as subject-matter for which the ISA and/or the IPEA is not required to carry out search and international preliminary examination.

Art. 17(2)(a)(i) Art. 34(4)(a)(i) Rule 39 Rule 67.1 GL/ISPE 9.02-9.15

The criteria applied for the decision not to perform an international search are the same as for the European procedure. This means that the discretion of an ISA not to search subject-matter set forth in <u>Rule 39.1</u> is exercised by the EPO as ISA only to the extent that such subject-matter is not searched under the provisions of the EPC.

For subject-matter which the ISA is not required to search under Art. 17(2)(a)(i) and where, as a consequence, an incomplete search report

will be issued, the restriction should always be indicated both in the search report and in the WO-ISA.

GL/ISPE 9.40

Where the subject-matter of all claims constitutes a subject excluded from the search, a declaration of non-establishment of the international search report is issued pursuant to Article.17(2)(a) on Form PCT/ISA/203, indicating the reasons. A written opinion is established, even though, in the absence of a search, it cannot address the questions of novelty and inventive step and may not be able to address other questions, such as that of industrial applicability. The written opinion should contain full reasoning as to why the search is not possible.

2.1 Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body

Rule 39.1(iv) GL/ISPE 9.08-9.10 Claims directed to medical treatment which would fall under the exceptions to patentability under <u>Art. 53(c) EPC</u> should, in principle, also be exempted from international search.

Yet the EPO as ISA applies the same practice as for European applications, and the examiner will explain so in the WO-ISA.

In the table below, several types of claim involving a composition A or substance X in methods of treatment or diagnosis (hereinafter referred to as medical treatment) are listed. Depending on the situation, some of these could be patentable in an EP application (see also GL/EPO G-VI, 7.1).

	Claim wording	Excluded from patentability according to Art. 53(c) EPC
а	compound X for use as a medicament	NO
b	compound X for use in treating disease Y	NO
С	composition A containing X for use in treating disease Y (composition A may be generally defined)	NO
d	medicament containing compound X	NO
е	use of X in a composition A for the treatment of disease Y	YES
f	use of X as a medicament for the treatment of disease Y	YES
g	use of X for the treatment of disease Y	YES
h	use of X for preparing a medicament	NO

	Claim wording	Excluded from patentability according to Art. 53(c) EPC
İ	use of X for the manufacture of a medicament for treating disease Y	NO
j	process for the preparation of a medicament for treating disease Y using compound X as an active ingredient	NO
k	method of treatment of disease Y using X	YES

For claims of type (a), (b) or (c), the examiner will search and examine the claims and give reasons with respect to the novelty and inventive step of the indicated uses as for an EP application. In the WO-ISA, a remark will be added that novelty and inventive step have been assessed according to EPO practice. The reason for adding this remark is that under Art. 54(4) and (5) EPC it is possible to obtain patent protection for any substance or composition comprised in the state of the art, for any use or specific use, respectively, in a (medical) method referred to in Art. 53(c) EPC, provided that such use is not comprised in the state of the art. Claims seeking this kind of protection may be drafted as "Substance X for use as a medicament/for use in therapy" or "Substance X for use in the treatment of disease Y", respectively. See also GL/EPO G-VI, 7.1.

For claims of type (d), (h), (i) or (j), the examiner will search and examine the claims and give reasons with respect to novelty and inventive step of the indicated uses as for an EP application. In the WO-ISA, a remark will be added that novelty and inventive step have been assessed according to EPO practice.

For claims of type (e), (f), (g) or (k), in the vast majority of cases, a search report is established on the basis of the alleged effects of the product/composition, because their subject-matter can readily and in a straightforward manner be understood in terms of these effects. For reasons of efficiency an opinion on novelty, inventive step and industrial applicability will be given for (at least) the independent claims, as far as relating to the alleged effects of the compound/composition, as would be done for an EP application. A reservation concerning patentability will be added, indicating that at the EPO claims directed to a method of treatment or the use of a composition in a treatment are exempted from patentability, but that a claim directed to a composition or substance for such use would be admissible.

In some cases, no search report can be established for claims of type (e), (f), (g) or (k), because their subject-matter cannot readily and in a straightforward manner be understood in terms of the alleged effects of the compound/composition. For these claims, no assessment under Art. 33(1), i.e. novelty, inventive step and industrial applicability, will be carried out.

Rule 33.3(b)

2.2 Subject-matter according to Rules 39.1(i), (iii), (v) and (vi)

Section B-VIII, 2.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

2.2.1 Computer-implemented business methods

OJ EPO 2014, A117 OJ EPO 2007, 592 OJ EPO 2010, 304 GL/ISPE 9.07 As a result of an amendment to the Agreement between the EPO and WIPO under the PCT, any national or resident of the United States of America filing an international application on or after 1 January 2015 with the United States Patent and Trademark Office (USPTO) or the IB as receiving Office will be able to select the EPO as ISA irrespective of the technical field in which the application is classified. It should, however, be noted that the Notice from the EPO dated 1 October 2007 concerning business methods remains applicable. Therefore, the EPO as ISA will, in all cases where the subject-matter of the international application involves technical means, consider the application and to the extent possible provide a search report for those parts of it which are more than mere business methods.

Section B-VIII, 2.2.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3. No meaningful search possible

The meaning of the word "meaningful" in the context of Art. 17(2)(a)(ii) is essentially a matter for the examiner to decide. The examiner's finding may change in the light of any reply from the applicant to the invitation for informal clarification, if available (see GL/PCT-EPO B-VIII, 3.3 and 3.4). The exercise of the examiner's discretion will depend upon the facts of the case.

GL/ISPE 9.01

The term "meaningful search" in <u>Article 17(2)(a)(ii)</u> should be read to include a search that within reason is complete enough to determine whether the claimed invention complies with the substantive requirements, that is, the novelty, inventive step, and industrial applicability requirements, and/or the sufficiency, support and clarity requirements of <u>Articles 5</u> and <u>6</u>. Accordingly, a finding of "no meaningful search" should be limited to exceptional situations in which no search at all is possible for a particular claim, for example where the description, the claims or the drawings are totally unclear. To the extent that the description, the claims or the drawings can be sufficiently understood, even though parts of the application are not in compliance with the prescribed requirements, a search should be performed recognising that the non-compliance may have to be taken into account for determining the extent of the search.

As there is no legal provision providing that an applicant must formulate the application in such a way as to make an economical search possible, "reasons of economy" cannot be used as a reason, or part of a reason, for issuing an incomplete search report.

3.1 Examples of impossibility to perform a meaningful search over the whole of the claimed scope

A number of non-limiting examples will illustrate where a restriction of the search may find application:

(i) claims lacking support; insufficient disclosure

Art. 5 and 6

One example would be the case of a broad or speculative claim supported by only a limited disclosure covering a small part of the scope of the claim. This could be the case if the broadness of the claim is such as to render a meaningful search over the whole of the claim impossible, and where a meaningful search could only be performed on the basis of the narrower, disclosed invention. This may mean a search of the specific examples. In such a case, it will often be de facto impossible to do a complete search of the whole of the claim at all, because of the broad drafting style. The examiner should bear in mind that the requirements under Art. 5 and 6 concerning sufficiency of disclosure and support should be seen in relation to the person skilled in the art.

(ii) claims lacking conciseness

An example would be where there are so many claims, or so many possibilities within a claim, that it becomes unduly burdensome to determine the matter for which protection is sought (for the case of multiple independent claims in the same category see <u>GL/PCT-EPO B-VIII. 4</u>). A complete search (or any search at all) may de facto be impossible.

Art. 6 Rule 6.1(a) GL/ISPE 9.25 and 9.30

It is noted that the EPO allows multiple dependent claims, provided that they do not detract from the clarity of the claims as a whole and that the arrangement of claims does not create obscurity in the definition of the subject-matter to be protected (see also GL/PCT-EPO F-IV, 3.4). In case of unclarity, it may be appropriate for the examiner to first invite the applicant for informal clarification before the search is carried out (see GL/PCT-EPO B-VIII, 3.3-3.6).

Rule 6.4(a) GL/ISPE 9.41

(iii) claims lacking clarity

An example would be where the applicant's choice of parameter to define his invention renders a meaningful comparison with the prior art impossible, perhaps because the prior art has not employed the same parameter, or has employed no parameter at all. In such a case, the parameter chosen by the applicant may lack clarity (see Art.6; cf. GL/PCT-EPO F-IV.4.11). It may be that the lack of clarity of the parameter is such as to render a meaningful search of the claims or of a claim or of a part of a claim impossible, because the choice of parameter renders a sensible comparison of the claimed invention with the prior art impossible. If so, the search may possibly be restricted to the worked examples, as far as they can be understood, or to the way in which the desired parameter is obtained.

GL/ISPE 9.22

In all examples listed above, the examiner may where appropriate informally invite the applicant to provide clarification of the claimed subject-matter (see GL/PCT-EPO B-VIII, 3.3).

See ISPE Guidelines 9.01 and 9.19-9.30 for further information.

3.2 Nucleotide and amino acid sequences

Rule 5.2, 13ter.1 OJ EPO 2007, Spec. ed. 3, C.2 OJ EPO 2011, 372 OJ EPO 2013, 542 GL/ISPE 9.39, 15.13 If the sequence listing of an international application is not available in electronic form and/or does not comply with the standard provided in Annex C to the Administrative Instructions (WIPO Standard ST.25), the EPO as ISA will invite the applicant to furnish the sequence listing in electronic text format and pay a late furnishing fee within a non-extendable time limit of one month from the date of the invitation.

If, within the time limit set, the applicant has not submitted the sequence listing in the required electronic form and format and paid the late furnishing fee, the EPO as ISA will carry out the international search without the sequence listing to the extent that a meaningful search can be carried out.

The examiner when performing the search will either:

issue a declaration under <u>Art. 17(2)(a)(ii)</u> and <u>Rule 13ter.1(d)</u> that no meaningful search on any claimed subject-matter is possible due to the failure of the applicant to comply with <u>Rule 5.2</u> (no sequence listing) and/or <u>Rule 13ter.1(a)</u> (no computer-readable sequence listing);

or

(ii) issue an incomplete search report with a declaration under Art. 17(2)(b) and Rule 13ter.1(d) that a meaningful search is not possible in respect of certain claimed subject-matter due to the failure to comply with Rule 5.2 (no sequence listing) and/or Rule 13ter.1(a) (no computer-readable sequence listing).

This also has consequences for the international preliminary examination procedure before the EPO as IPEA (see <u>GL/PCT-EPO C-VIII, 2.1</u>).

3.3 Informal clarification

GL/ISPE 9.34, 9.35

Where the description, claims or drawings fail to comply with a requirement, such as clarity or support of the claims by the description, to such an extent that no meaningful search can be made, the examiner may informally contact the applicant to clarify specific aspects of the application before the search is carried out. Such informal clarification may help the examiner to focus the search better. It is highly recommended to invite the applicant to provide such informal clarification before issuing an incomplete ISR or a declaration of no search. However, there is no legal obligation on the examiner to use it and no legal consequences in the PCT if the applicant does not respond. An incomplete search report or a declaration of no search may still be issued without prior clarification.

Informal clarification may take the form of a telephone consultation or of a written request (Form PCT/ISA/207) sent by fax. In both cases the applicant can be given a short time limit (normally two weeks) to respond. In view of the short time limits in the PCT, a telephone consultation, for which minutes must be written, may be more appropriate. If the issues at stake can be clarified during the telephone consultation, no time limit will be given. The examiner will send the minutes of the consultation for information and will prepare the ISR and WO-ISA taking the result of the consultation into account.

Alternatively, a written request for clarification can be sent by fax. This is in particular appropriate when dealing with non-European representatives due to potential time zone differences and linguistic problems, and/or when the issue to be discussed is not suitable for a telephone consultation.

3.4 Reply to the invitation for informal clarification

3.4.1 Failure to reply in time or no reply

If the applicant does not reply within the set time limit to the invitation for informal clarification, the examiner will prepare the search report and WO-ISA to the extent possible without the requested clarification.

If the applicant replies after the time limit has expired, and the search report has not yet been established, the reply should be taken into account; if the search report has already been established the reply will not be taken into account

3.4.2 Reply in time

If the applicant replies to the invitation for informal clarification, the examiner will prepare the search report and WO-ISA taking the reply into account.

3.5 The content of the WO-ISA after an invitation for informal clarification and/or in case of a restriction of the search

Generally, a restriction of the search will not always be indicated in the international search report. Rather the extent of the search as well as the reasons for the restriction will in many cases only be indicated in the WO-ISA, as explained below. The opinion given is normally restricted to what has actually been searched.

Art. 17(2)(b)

If after clarification a complete search can be made, the ISR will be designated as complete. Any outstanding clarity problem will be mentioned in Box VIII of the WO-ISA.

If only some of the claims and/or parts of the claims can be searched and it is not possible, on the basis of the description, to foresee a likely fallback position for the unsearched subject-matter, even taking any reply from the applicant into consideration, a precise indication of what has been searched with the corresponding claims, together with full reasoning why the search was restricted, are entered into both the ISR and the WO-ISA. In

Art. 17(2)(b)

addition, in the WO-ISA an opinion as to novelty, inventive step and industrial applicability of the searched subject-matter must be given.

If some claims or parts of claims cannot be searched but it is possible, on the basis of the description, to foresee a searchable fallback position, taking any possible reply from the applicant into consideration, the ISR will be filled out as for a complete search in respect of those claims. An indication which claims have been searched (in part), together with full reasoning why the search was restricted, and a precise indication of what has been searched are entered into the WO-ISA. In the ISR the cited documents will relate to the searched (or partially searched) claims only. In addition, in the WO-ISA an opinion as to novelty, inventive step and industrial applicability of the searched subject-matter must be given.

Art. 17(2)(a)(ii)

If, even taking any reply from the applicant into consideration, it is not possible to perform a search at all, a declaration of no search, together with full reasoning why, is issued instead of the ISR. The WO-ISA must contain full reasoning why the search is not possible.

Rule 39

A restriction of the search due to exceptions mentioned in <u>Rule 39</u> (e.g. medical treatment claims) must always be indicated in the search report.

Rule 13 Art. 17(2)(a)(ii)

3.6 Combination of an incomplete search and lack of unity

The requirements of unity of invention and the requirements of Art. 17(2)(a)(ii) are separate requirements. However, it is possible that an application both violates the requirements of clarity, disclosure, support or conciseness to such an extent that a meaningful search cannot be carried out, and lacks unity. In that case, the examiner can combine an incomplete search and a finding of non-unity. However, the applicant should not be invited to pay additional fees for subject-matter which will later not be searched under Art. 17(2)(a)(ii). Typically, a non-unity objection could be made first and then an incomplete search applied to the searched invention. In such a case the examiner may send an informal clarification request for the first invention only and include in the invitation to pay additional fees remarks on clarity problems related to further inventions.

However, if the complexity lies in lack of clarity, the search will be restricted first, and the non-unity objection applied to the clear parts of the claimed subject-matter.

4. Multiple independent claims per category

GL/ISPE 5.13-5.14

Multiple independent claims in one category are per se not a reason for an incomplete search

Generally, an opinion must be given on all searched claims. Only one independent claim in each category needs to be treated in detail; short comments would normally suffice for further independent claims.

Furthermore, if appropriate, an objection as to clarity and conciseness under <u>Article 6</u> may be made under Box VIII of the WO-ISA. The EPO as ISA may exercise its discretion to ask the applicant to clarify the subject-

matter to be searched, applying the same procedure as described under $\underline{\text{GL/PCT-EPO B-VIII}}$, 3.3-3.4.

Chapter IX - Search documentation

1. General

1.1 Organisation and composition of the documentation available to the Search Divisions

Section B-IX, 1.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

1.2 Systematic access systems

Section B-IX, 1.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

2. Patent documents arranged for systematic access

2.1 PCT minimum documentation

Section B-IX, 2.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 34.1(b)(i), (ii) and Rule 34.1(c)

2.2 Unpublished patent applications

Since the search for conflicting applications that are not published at the time of the initial search is completed either during <u>Chapter II</u> in case a demand is filed or during the European phase, the documents which can be cited in the search report do not include unpublished patent applications (see <u>GL/PCT-EPO B-VI, 4.1</u>).

2.3 Search reports

Section B-IX, 2.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

2.4 Patent family system

Section B-IX, 2.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3. Non-patent literature arranged for systematic access

3.1 Periodicals, records, reports, books, etc.

Section <u>B-IX, 3.1, in the Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

4. Non-patent literature arranged for library-type access

Section B-IX, 4.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

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Chapter X - Search report

1. General

The results of the search will be recorded in an international search report. A number of different possible limitations of the scope of the search report exist. These are:

- (i) a declaration issued instead of the search report according to Art. 17(2)(a) (see GL/PCT-EPO B-VIII);
- (ii) an incomplete search report according to Art. 17(2)(b) (see GL/PCT-EPO B-VIII);
- (iii) a partial international search report due to a finding of a lack of unity according to Art. 17(3)(a) and Rule 13; and
- (iv) an incomplete search report due to missing sequence listings (see GL/PCT-EPO B-VIII, 3.2).

The Search Division is responsible for drawing up the international search report (see <u>GL/PCT-EPO B-I, 2</u> and subsections).

This chapter contains the information which is necessary to enable the examiner to correctly prepare the search report.

A search report must contain no matter, in particular no expressions of opinion, reasoning, arguments or explanations, other than that required by the Form or referred to in <u>GL/PCT-EPO B-X, 9.2.8</u>. However, this does not apply to the written opinion (see <u>GL/PCT-EPO B-XI, 3</u>).

Rule 43.9 GL/ISPE 16.07

2. Different types of search reports drawn up by the EPO as ISA

The EPO in its capacity as ISA will draw up the following types of search reports:

(i) international search reports under the PCT;

Art. 16(1)

(ii) international-type search reports. For details, reference is made to GL/EPO B-II, 4.5.

Art. 15(5) GL/ISPE 2.22, 16.04

3. Form and language of the search report

3.1 Form

See ISPE Guidelines 16.08 and 16.09.

Rule 43.10

3.2 Language

See ISPE Guidelines 16.11.

Rule 43.4

3.3 Account of the search

Section B-X, 3.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4. Identification of the patent application and type of search report Section B-X, 4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

5. Classification of the patent application

Rule 43.3(a) GL/ISPE 16.52 The EPO as ISA classifies the application according to the IPC and CPC.

6. Areas of technology searched

GL/ISPE 16.53

Section B-X, 6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

7. Title, abstract and figure(s) to be published with the abstract (as indicated on supplemental sheet A)

Rule 44.2 GL/ISPE 16.33 The international application must contain an abstract and a title (see also <u>GL/PCT-EPO F-II, 2</u> and <u>3</u>). If the search report is published together with the application (A1 publication), the examiner indicates on supplemental sheet A:

Rule 8.1, 38 GL/ISPE 16.35-16.43 the approval or amendment of the text of the abstract, which should not exceed 150 words;

Rule 37 GL/ISPE 16.44, 16.47 (ii) the approval or amendment of the title of the invention. The procedure is the same as for EP files (see GL/EPO B-X, 7); and

Rule 8.2 GL/ISPE 16.48-16.51 (iii) the figure which is to accompany the abstract. It is possible to indicate multiple figures from various sheets, but the overall size should not exceed what could fit on an A4 sheet.

GL/ISPE 15.40

If the application is to be published before the international search report is prepared (A2 publication, see <u>GL/EPO B-X, 4</u>), the examiner only needs to prepare the classification data. Titles, abstracts and figures are published as submitted by the applicant.

It is to be noted that first filings (i.e. applications not claiming priority from an earlier application) cannot be published as A2.

8. Restriction of the subject of the search

GL/ISPE 16.19 GL/ISPE 16.28-16.32 In the following cases, the international search report, the declaration issued instead of the search report under Art. 17(2)(a), or the incomplete or partial search report will indicate whether the subject of the search was restricted and which claims have or have not been searched:

Art. 17(3)(a), Rule 13

- (i) lack of unity of invention (see <u>GL/PCT-EPO B-VII</u>).
- (ii) claims in respect of which no meaningful search or only an incomplete search can be carried out (see GL/PCT-EPO B-VIII).

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In case (ii), the following situations may occur:

(a) A declaration that a meaningful search has not been possible <u>Art. 17(2)(a)</u>
 on the basis of all claims is issued instead of the search report;
 or

(b) If a meaningful search has not been possible for one or more <u>Ar</u> of the claims in part or in full, the claims concerned are mentioned in the incomplete search report and/or in the written opinion.

Art. 17(2)(b)

In case (a), the reasons for not carrying out the search should be indicated in the declaration.

In case (b), a limitation of the search will not always be indicated in the ISR. Rather, the extent of the search as well as the reasons for the restriction will in many cases only be indicated in the WO-ISA. See <u>GL/PCT-EPO B-VIII, 3.5</u>, for details of whether an indication under Art. 17 should be made in the ISR or only in the WO-ISA.

(iii) missing sequence listings (see GL/PCT-EPO B-VIII, 3.2).

Rule 5.2, 13ter.1

9. Documents noted in the search

9.1 Identification of documents in the search report

9.1.1 Bibliographic elements

Section B-X, 9.1.1, in the Guidelines for Examination in the EPO applies GL/ISPE 16.78 mutatis mutandis.

9.1.2 "Corresponding documents"

Section B-X, 9.1.2, in the Guidelines for Examination in the EPO applies Rule 33.1 mutatis mutandis.

Rule 33.1

GL/ISPE 16.64(a)

9.1.3 Languages of the documents cited

Section B-X, 9.1.3, in the Guidelines for Examination in the EPO applies *GL/ISPE 15.69, 15.72* mutatis mutandis.

9.2 Categories of documents (X, Y, P, A, D, etc.)

Section B-X, 9.2, in the Guidelines for Examination in the EPO applies Section 505 PCT AI mutatis mutandis.

Section 505 PCT AI GL/ISPE 16.65

9.2.1 Particularly relevant documents

Section B-X, 9.2.1, in the Guidelines for Examination in the EPO applies GL/ISPE 16.66-16.68 mutatis mutandis.

9.2.2 Documents defining the state of the art and not prejudicing novelty or inventive step

Section B-X, 9.2.2, in the Guidelines for Examination in the EPO applies GL/ISPE 16.69 mutatis mutandis.

9.2.3 Documents which refer to a non-written disclosure

GL/ISPE 16.70 Section B-X, 9.2.3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

9.2.4 Use of "P" documents in the search report

Rule 33.1(c) GL/ISPE 11.07 Although "P" documents are normally not used for the further examination they should be indicated in the search report since they might become pertinent at a later national stage. The EPO as ISA also cites non-patent literature P-X documents in the search report. If the priority document is not available to the examiner at the time of the search, it will be assumed that the priority is valid for the purpose of establishing the search report and written opinion. For the relevant dates for conducting the search, see GL/PCT-EPO B-VI, 3.

GL/ISPE 16.71

Furthermore, section <u>B-X</u>, <u>9.2.4</u>, in the <u>Guidelines for Examination in the EPO applies *mutatis mutandis*.</u>

9.2.5 Documents relating to the theory or principle underlying the invention

GL/ISPE 16.72

Section B-X, 9.2.5, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

9.2.6 Potentially conflicting patent documents

GL/ISPE 16.73

Section B-X, 9.2.6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

9.2.7 Documents cited in the application

See GL/ISPE 16.74.

9.2.8 Documents cited for other reasons

GL/ISPE 16.75 GL/ISPE 11.10 Section B-X, 9.2.8, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

9.3 Relationship between documents and claims

GL/ISPE 16.77

Section B-X, 9.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

9.4 Identification of relevant passages in prior art documents

Rule 43.5(e) GL/ISPE 15.69 , GL/ISPE 16.64(b) Section B-X, 9.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

10. Authentication and dates

Rule 43.2, 43.8 GL/ISPE 16.83-16.84 Section B-X, 10, in the Guidelines for Examination in the EPO applies mutatis mutandis.

11. Copies to be attached to the search report

11.1 General remarks

Rule 44.1 and 44.3 GL/ISPE 16.86 One copy of the international search report is sent to the IB and one to the applicant. The latter is accompanied by copies of all documents cited, except those documents appearing in the search report after the "&"

symbol, which are not designated for copying and communication to the applicant (see GL/EPO B-X, 11.3).

11.2 Electronic version of document cited

Section B-X, 11.2, in the Guidelines for Examination in the EPO applies mutatis mutandis.

11.3 Patent family members; the "&" sign

Section B-X, 11.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

11.4 Reviews or books

Section B-X, 11.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

11.5 Summaries, extracts or abstracts

Section B-X, 11.5, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

11.6 Citation of video and/or audio media fragments available on the internet

Section B-X, 11.6, in the Guidelines for Examination in the EPO applies mutatis mutandis.

12. Transmittal of the search report and written opinion

The EPO forwards one copy of the search report or the declaration under Art. 17(2)(a) and of the written opinion to the IB and one copy to the applicant. The applicant also receives copies of all cited documents see GL/EPO B-X, 11.1), including automated translations annexed to the written opinion (when appropriate, see GL/EPO B-X, 9.1.3) and those documents appearing after the "&" sign and designated to be copied and sent to the applicant (see GL/EPO B-X, 11.3).

Rule 44 GL/ISPE 16.86

Chapter XI - The written opinion

1. The written opinion

Under <u>Chapter I</u>, at the same time as establishing the search report the search examiner must establish the written opinion of the ISA (WO-ISA) to be sent to the applicant together with the search report. The WO-ISA gives a preliminary and non-binding opinion on whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable. When appropriate, an opinion will also be given on added subject-matter, unity, insufficient disclosure and clarity or support issues, as well as formal defects.

Rule 43bis GL/ISPE 17

The findings of the written opinion must be consistent with the document categories assigned in the search report and must also be consistent with any other issues raised in the search report, such as lack of unity of invention or limitation of the search.

If there are no defects in the application, the WO-ISA will state the reasons why the application is considered to fulfil the requirements of novelty, inventive step and industrial applicability.

The written opinion (and any informal comments filed by the applicant) will be made available to the public by the IB at the same time as the international publication.

Art. 21(3) GL/ISPE 2.17

If the application subsequently enters the EP phase, the applicant is obliged to reply to any negative WO-ISA or IPRP/IPER. The WO-ISA is thus comparable to the ESOP in the European procedure.

2. Basis of the written opinion (WO-ISA)

The applicant cannot amend his application before the search report has been communicated to him. Consequently, the WO-ISA will always relate to the application documents as originally filed or a translation thereof, and subject to the possibility of sequence listings being furnished later for the purposes of international search (see <u>Rule 13ter.1</u>). Furthermore, any reply filed by the applicant in response to an invitation for informal clarification (see <u>GL/PCT-EPO B-VIII, 3.4</u>) will also be taken into consideration when drawing up the written opinion.

GL/ISPE 17.13

Replacement pages or sheets, filed in response to an invitation by the receiving Office to correct defects in the international application, are deemed to be part of the international application "as originally filed". These sheets are identified with a stamp "SUBSTITUTE SHEET (RULE 26)" (see GL/PCT-EPO H-IV, 1). Also, replacement pages or sheets for rectification of obvious mistakes under Rule 91 (see GL/PCT-EPO H-IV, 2) are deemed to be part of the international application "as originally filed". These sheets are identified with "RECTIFIED SHEET (RULE 91.1)".

Rule 26 Rule 91.1 GL/ISPE 17.16

See <u>GL/PCT-EPO H-IV, 2</u>, for the procedure to follow if the rectified sheets contain added subject-matter.

Rule 20.6 GL/ISPE 15.11

2.1 Applications containing missing parts furnished under Rule 20

An applicant that has omitted to file parts of the application may still furnish them at a later date without affecting the international filing date, subject to the requirements of <u>Rules 4.18</u> and <u>20.6(a)</u> and provided the missing part(s) were completely contained in the priority document. The examiner must check (as far as the documents needed are available) whether the RO's assessment of the "completely contained" criterion was correct (see <u>GL/PCT-EPO H-II, 2.2.2</u>).

If these part(s) were indeed completely contained in the priority document (or if the priority document and any other document needed is/are not available), the examiner will treat the file as having the filing date accorded by the RO. If the documents needed for the check are not available, this will be indicated in the WO-ISA, in Section I of the separate sheet.

If these part(s) were not completely contained in the priority document, the decision on the filing date made by the RO is still valid for the international phase. However, the examiner will indicate in the WO-ISA under Section I on the separate sheet that there are doubts as to whether the missing part(s) were actually completely contained in the priority document. The search report and WO-ISA will also include documents which would be relevant if the application were to be redated (see <u>GL/PCT-EPO B-III, 2.3.3</u>).

3. Analysis of the application and content of the written opinion

3.1 The examiner's dossier

Section B-XI, 3.1 in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3.2 Reasoned objections

3.2.1 Opinion on novelty, inventive step and industrial applicability The opinion given in the WO-ISA is restricted to what has actually been searched; this should also be made clear in the WO-ISA.

A full explanation of the conclusions reached should always be given for all searched claims, regardless of whether this conclusion is positive or negative. Normally only one independent claim in each category is treated in detail; for negative conclusions regarding further independent claims, as well as for dependent claims, comments may be shorter.

3.2.2 Multiple independent claims

GL/ISPE 5.13 and 5.14

Multiple independent claims in one category are per se not a reason for a restriction of the search (see <u>GL/PCT-EPO B-VIII, 4</u>).

If appropriate, an objection as to clarity and conciseness under <u>Article 6</u> may be made under Box VIII (see <u>GL/PCT-EPO F-IV, 3.2</u>).

3.2.3 Dependent claims - WO-ISA

Dependent claims should be indicated as complying or not with the requirements of novelty, inventive step and industrial applicability. Short statements of the reasons why the claims do not comply with these requirements should be given on the separate sheet. At the discretion of the examiner, more detailed comments may be made about selected dependent claims. If any claims are found to be novel and inventive, brief reasons for this too should be given on the separate sheet.

3.2.4 Clarity, conciseness, support and formal defects – WO-ISA

Major clarity, conciseness or support issues will be mentioned under Box VIII, unless they result in a meaningful search being impossible, in which case they will be treated under Section III.

Formal defects (e.g. reference signs, two-part form, acknowledgment of prior-art documents, etc.) as well as minor clarity issues will be dealt with under Boxes VII and VIII respectively.

If the application is severely deficient and it is clear that the claims will have to be drastically redrafted anyway, it is not necessary to make objections with respect to minor clarity issues and/or formal issues.

3.3 Making suggestions

It is possible to make suggestions in the written opinion as to how certain objections raised may be overcome. However, the examiner must not actually, of his own volition, make any final amendments to the application documents, however minor, for the reason that only amendments submitted by the applicant may be taken into consideration for the IPER. In no circumstances should the impression be given that compliance with the suggestions would lead to an allowable application under the EPC or any national law.

If no demand for <u>Chapter II</u> is filed, the WO-ISA will automatically be converted into an IPRP <u>Chapter I</u>. Therefore, the WO-ISA should not contain formulations suggesting to the applicant to actively file submissions.

3.4 Positive or negative WO-ISA

The examiner needs to indicate whether the WO-ISA is to be considered positive or negative for further prosecution. The reason for this is that when entering the European phase the applicant is required to respond to the WO-ISA if it is negative, but not if it is positive (see <u>GL/EPO E-VIII, 3.3.2</u>).

As a general rule, a WO-ISA is considered positive if it contains no objections at all or only minor objections which would not hinder a direct grant in the EP phase (see also <u>GL/EPO C-V, 1.1</u>).

In the special case where the search report cites P and/or E documents but the priority could not be checked and there are no other objections, the WO-ISA is considered positive (since the examiner in the European phase first has to evaluate the validity of the priority and then decide whether a grant is still possible). GL/ISPE 3.05, 17.71

On the other hand, if the relevance of the document is independent of the priority being valid, detailed reasons for the novelty objection will be given, as well as an indication to the applicant that such a document would be relevant when entering the European phase before the EPO.

In the case of method of treatment claims which can easily be reformulated into an allowable format (see also <u>GL/PCT-EPO B-VIII, 2.1</u>), the above applies as well; i.e. if this is the only objection, the WO-ISA will be considered positive since such a reformulation can be done by the examiner at the grant stage in the European phase before the EPO.

In the special case of a non-unitary application, where all inventions searched were found to be novel and inventive, but still lacking unity - as the only objection - the WO-ISA is marked as negative.

4. Priority claim and the WO-ISA

GL/ISPE 17.28-17.29

Normally, priority need only be checked if a relevant P or E document is found during the search. However, there may also be cases where the examiner immediately realises that the priority is not valid (e.g. in the case of an alleged doublure (see <u>GL/PCT-EPO B-IV, 1.1</u>) or a continuation-in-part (see <u>GL/PCT-EPO F-VI, 1.4</u>)). Also, in case of restoration of priority rights, the examiner may insert a comment in Box II (see <u>GL/PCT-EPO B-XI, 4.1</u>).

4.1 Restoration of priority

Rule 26bis.3

See GL/PCT-EPO F-VI, 3.7.

If the examiner notices that the filing date exceeds the earliest priority date plus twelve and two months this may be indicated in the WO-ISA.

4.2 Use of "P" documents in the written opinion

GL/ISPE 17.29(b)

If the priority document is not available, the opinion will be established on the assumption that the claimed priority is valid. In this case, no comments need be made regarding "P" documents, but the "P" documents will nevertheless be indicated under Section VI. For potentially conflicting patent documents which might give rise to an objection under Art. 54(3) EPC in the European phase, the statements in GL/PCT-EPO B-XI, 4.3, below regarding "E" documents apply.

GL/ISPE 17.29(c)

If the priority document is available, the examiner will check the validity of the priority and indicate any negative finding under Section II. Should the priority be found not to be valid, detailed comments will be made for these documents with respect to novelty and inventive step of the claimed subject-matter under Section V, since these documents then become prior art under Rule 33.1(a).

Sometimes it is possible for the examiner to determine from the documents on file that the claimed priority is not valid. An example would be when during the search a document is found which shows that the priority document of the searched application is actually not the first application for the claimed invention.

4.3 Use of "E" documents in the written opinion

Although there are no harmonised provisions in the PCT Contracting States that correspond to Art. 54(3) EPC, such documents will be mentioned under Section VI if they are considered prejudicial to the novelty of at least one claim. If the relevance of the document is independent of the priority being valid or if the priority could be checked and was found invalid, reasons for the novelty objection will be provided, together with an indication that such a document would be relevant when entering the European phase before the EPO.

On the other hand, if the document would be relevant under <u>Art. 54(3) EPC</u> only if the priority is not valid, and this could not be checked, then no reasons need to be given.

5. Unity in relation to the written opinion

In the case of lack of unity where more than one invention has been searched, for each invention searched one independent claim in each category must be treated in detail.

See GL/PCT-EPO B-VII for further details.

6. The written opinion in cases of a restriction of the search

The extent of the search as well as the reasons for the restriction will in many cases only be indicated in the WO-ISA. See <u>GL/PCT-EPO B-VIII, 3.5</u>, for details of whether an indication under <u>Art. 17</u> should be made in the ISR or only in the WO-ISA. The opinion given is then normally restricted to what has actually been searched.

Any argumentation and objections presented in the written opinion must be consistent with the restrictions of the search and the reasons therefor. See also GL/PCT-EPO B-VIII, 2, 3 and 3.1.

7. Sequence listings

Where the applicant has not filed an electronic sequence listing conforming to WIPO Standard ST.25 in response to a request from the ISA, or has not paid the late furnishing fee, the WO-ISA will indicate under Section III that the written opinion is limited to the same extent as the search was limited because the applicant failed to comply with <u>Rule 5.2</u> (no sequence listing) and/or <u>Rule 13ter.1(a)</u> (no computer-readable sequence listing).

Rule 5.2 Rule 13ter.1(a) OJ EPO 2011, 372 OJ EPO 2013, 542 GL/ISPE 9.39, 15.12 and 15.13

8. Options open to the applicant following receipt of the ISR and WO-ISA

See ISPE Guidelines 2.15.

If the international application subsequently enters the European phase, the applicant is obliged to reply to any negative WO-ISA or IPER.

Chapter XII – Supplementary international search (SIS)

1. General

The supplementary international search system is optional for both applicants and International Authorities. Its purpose is to enable applicants, during the international phase, to obtain further supplementary searches from other Authorities so that they have a better basis for deciding whether or not to enter the regional phase.

Rule 45bis OJ EPO 2010, 304 OJ EPO 2010, 316 OJ EPO 2014, A117 GL/ISPE 2.20, 15.76

The EPO as SISA only accepts a limited number of SIS requests per year. Since 2010, the EPO has limited the number of SIS requests it will accept to 700 per year.

2. Time limits

An applicant can request a SIS up to the end of 19 months from the priority date. The request must be filed with the IB.

Rule 45bis.1(a) GL/ISPE 2.20, 15.78

The SISA must start the search promptly after receipt of the necessary documents, though it may delay the start of the search until it has received the ISR from the main ISA, but not later than the end of 22 months from the priority date.

Rule 45bis.5(a) GL/ISPE 15.82

The supplementary international search report (SISR) must be established within 28 months from the priority date so as to allow the applicant to take it into account when deciding whether or not to enter the regional/national phase.

Rule 45bis.7(a) GL/ISPE 15.94

The file will therefore be sent to the examiner as soon as all the documents have been received, including the ISR from the main ISA. If, however, the ISR from the main ISA is not received within 22 months from the priority date, the file will be sent to the examiner to enable him to start the search.

3. Basis for the search

The SIS is always made on the claims as originally filed (or a translation thereof), irrespective of whether amendments have been filed under <u>Art. 19</u> or <u>34</u>.

Rule 45bis.5(b) GL/ISPE 15.85

4. Scope of the search

At the EPO the scope of a SIS is the same as for any other international search carried out by the EPO as ISA and is not limited to documentation in a specific language.

GL/ISPE 15.93

If an ISR from the main ISA is already available when the examiner carries out the SIS, it will be taken into account when establishing the SISR and written opinion.

5. Limitation of the search for reasons other than non-unity

With respect to limitations of the search for reasons other than non-unity (including the issuance of a declaration of no search), the same criteria

GL/ISPE 15.87

apply as for any international search carried out by the EPO as ISA (see GL/PCT-EPO B-VIII, 2, 3 and subsections).

Any such limitation of the search will be indicated in the search report and/or the annexed explanations (of equal value to the information contained in a WO-ISA) as set out in <u>GL/PCT-EPO B-X. 8</u>, and <u>B-XI, 6</u>, with the exception that in the case of a declaration of no search (Form PCT/SISA/502) no explanations from the SISA are provided for. For any other limitation of the search, the reasoning will be given only in the explanations annexed to the SISR and an automatic reference thereto will be inserted in the SISR.

Rule 45bis.5(d) and Rule 45bis.5(e) Furthermore, the SISA does not have to search claims which were not searched by the main ISA. However, the examiner will not limit the SIS merely on the grounds that the main ISA did so, but will make a case-by-case assessment based on EPO practice to determine whether the limitation made by the main ISA was appropriate under EPO practice.

For non-unity: see GL/PCT-EPO B-XII, 10.

6. Filling out the search report

GL/ISPE 15.96

The SISR is filled out in the same way as for any international search, with the exception that publication details do not have to be provided since the main ISA has already provided the publication data and IPC classes.

The examiner will not cite in the SISR a document already cited in the ISR unless he attaches a different significance to it, e.g. as a Y document in combination with a newly cited document or where the main ISR has clearly failed to recognise the extent of the document's relevance.

Furthermore, it will be indicated in the SISR whether or not the main ISR was available and taken into account.

7. Explanations under Rule 45bis.7(e)

Rule 45bis.7(e) GL/ISPE 15.96(iv), (v) No separate WO-ISA is established for a SIS. Instead, only a free-text sheet is used, and this will contain the same information as the separate sheet that is part of the WO-ISA in the form of "explanations". Upon entry into the European phase, the applicant is obliged to respond to these explanations, as set out in <u>Rule 161(1) EPC</u>. A positive conclusion must be reasoned in the same way as in a WO-ISA/IPER.

Formally, the explanations under <u>Rule 45bis.7(e)</u> are part of the SISR (Form PCT/SISA/501) and are contained in an annex called the "Scope Annex".

Although the Scope Annex will concentrate on the documents cited in the SISR, in some circumstances it might be appropriate to raise objections based on documents cited in the ISR.

An example would be that of a document cited in the ISR which could be used as a Y document for inventive step for some dependent claims in the

Scope Annex. In this case it might be necessary to cite the document again in the SISR as a Y document for those claims if this was not already indicated in the main ISR (see also <u>GL/PCT-EPO B-XII, 6</u>), and to provide argumentation in the Scope Annex.

It may also occur that although the EPO as SISA finds further pertinent prior art, objections may also be raised based on X and/or Y documents cited in the ISR. In such a case, the examiner may choose to base objections only on the documents cited in the ISR if considered expedient. Should the objections correspond to those raised in the WO-ISA from the main ISA, a mere reference to the WO-ISA objections will suffice.

There may also be cases where the ISR contains documents pertinent for novelty and/or inventive step and the EPO as SISA cannot find any further relevant documents (only possibly A documents). In such a case the following two possibilities will arise:

- (i) if the examiner agrees with the categories (X, Y) given in the ISR for these documents, it is not necessary to cite the documents again in the SISR. The examiner will then use the documents cited in the ISR to raise objections of lack of novelty and/or inventive step. If the WO-ISA from the main ISA has raised the same objections, and the examiner agrees with the given reasoning, a mere reference to the objections raised in the WO-ISA from the main ISA will suffice.
- (ii) if the examiner does not agree with some or all of the categories (X, Y, A) given in the ISR for any such documents considered pertinent and upon which the examiner wishes to base his objections in the Scope Annex, such documents will be cited again in the SISR.

In both these cases the A documents found by the EPO as SISA will be cited in the SISR.

Generally, an explicit re-evaluation of the objections raised in the WO-ISA will be avoided. The examiner will thus refrain from negatively commenting on any reasoning given in the WO-ISA, bearing in mind that national law differs amongst the PCT contracting states.

8. Validity of priority and E/P documents

At this stage the priority document should be available in the file and it can therefore be checked if E/P documents were found during the search. Should the priority document not be available, for the purposes of the search the priority is assumed to be valid. No indication in the Scope Annex is necessary.

If the priority is not valid, this will be explained in the Scope Annex, and any P documents found to be relevant will be dealt with in detail.

On the other hand, if the priority is valid, any cited P documents do not need to be dealt with in detail.

Any E document which is a potential <u>Art. 54(3) EPC</u> document will be dealt with in the Scope Annex. In this case the applicant's attention should be drawn to the relevance of such a document if the application enters the European phase before the EPO and a reasoned statement as to lack of novelty will be given.

9. Copies of documents cited in the SISR

OJ EPO 2010, 316 GL/ISPE 15.97 The applicant will receive a copy of each document cited in the SISR free of charge.

10. Non-unity

10.1 General procedure

Rule 45bis.6 GL/ISPE 15.89-15.90 In case of non-unity only one invention is searched; there is no possibility to pay additional fees for further inventions. Furthermore, the decision as to which invention should be considered the main invention and thus searched is handled differently for the SIS procedure, as set out in detail in GL/PCT-EPO B-XII, 10.2.

Rule 45bis.1(d)

Where the main ISA has already objected to lack of unity, the applicant can indicate together with the supplementary search request which of the inventions should be searched by the SISA. For further details see GL/PCT-EPO B-XII, 10.3.

Rule 45bis.6(b)

If on the other hand the main ISA has not objected to lack of unity, the EPO as SISA is free to do so, as the SISA is not bound by any finding on unity made by the ISA but merely obliged to take such a finding into account.

Rule 45bis.6(c)

As for any international search where lack of unity is objected to, the applicant has the right to protest against the non-unity finding. In the SIS procedure this protest is called a review (see <u>GL/PCT-EPO B-XII, 10.4</u>).

10.2 Deciding what is to be considered the main invention

The main invention will normally be the invention first mentioned in the claims. However, the examiner will exercise due discretion in selecting the invention to be searched where the first mentioned invention is one for which no search report would be established, or else where the applicant has requested that the supplementary search should be limited to one of the inventions other than the first identified by the ISA responsible for the main international search. For details, see GL/PCT-EPO B-XII, 10.3.

10.3 The main ISA found that unity of invention is lacking

If the main ISA has already objected to lack of unity and the examiner agrees with the assessment in the main ISR, this can be reported by simply referring to the ISR.

If the examiner forms a different point of view, or agrees with a revised view on unity of invention in a decision relating to a protest before the ISA, the reasoning will be set out in full so that it is easily understood by both the applicant and third parties. No reasons need be given why the lack-of-unity objection raised in the ISR could not be followed.

If the examiner finds that the application does not lack unity, a complete search is made for all the claims. No reasons need be given why the lack-of-unity objection raised in the ISR could not be followed.

Furthermore, if the main ISA has already objected to lack of unity, the applicant can indicate, on the supplementary search request form (in Box IV), which of the inventions searched by the main ISA the SIS should be based upon.

If the examiner agrees with the assessment of unity of invention made by the main ISA and the relevant claims are not excluded for any reason, the SIS will focus on the invention indicated by the applicant.

If the examiner cannot follow the objection raised in the ISR, but raises a different non-unity objection, when deciding on the main invention to be searched, he will take the request by the applicant into account as far as possible. The examiner will provide complete reasoning for the lack-of-unity objection in the SISR and will include an explanation of the extent to which the applicant's request could be taken into account in view of the different non-unity objection raised by the EPO.

10.4 Review procedure

If the applicant does not agree with the finding of lack of unity he can request a review of this finding. This procedure is similar to the protest procedure with the difference that additional fees cannot be paid.

Rule 45bis.6(d) GL/ISPE 15.91

If the applicant requests a review of the non-unity finding he must pay a review fee. If no fee is paid, the request for review is considered not to have been made.

Similar to the protest procedure, a Review Panel is established consisting of the examiner responsible for the file, an examiner as chairperson of the Review Panel and a further examiner. This Review Panel will, in case of entry into the European phase, constitute the Examining Division (see <u>GL/PCT-EPO B-VII, 7.2</u>). The examiner dealing with the file will make a first assessment of the arguments made by the applicant and will then discuss the case with the members of the Review Panel to come to a decision.

The purpose of the Review Panel is to determine whether the lack-of-unity objection was justified on the basis of the reasoning given in the SISR. The review does not include re-evaluation to determine possible additional grounds for lack of unity.

Where the Review Panel determines that the objection was not justified, it will inform the applicant with Form 503; no reasoning needs to be given. Furthermore, it will order the reimbursement of the review fee. A corrected SISR must then be established on all claims.

If the Review Panel considers that the objection is completely or partially justified, it will communicate this to the applicant with Form 503. In these cases, reasoning must be given indicating why the objection is (at least

partially) upheld, including addressing the applicant's arguments to the extent reasonable. The review fee will not be reimbursed. In the case of an only partially justified lack-of-unity objection, a corrected search report taking the result of the review into account must be established.

11. Combination of SIS and Chapter II

If the ISA was one of the European International Searching Authorities (SE, ES, AT, FI, NPI (XN) or VPI (XV)) the applicant can file a demand under Chapter II with the EPO and additionally a request for SIS by the EPO.

For such a file the examiner will first establish the SISR with Scope Annex and then continue with <u>Chapter II</u>.

GL/ISPE 17.04

Under <u>Chapter II</u>, a WO-IPEA (Form 408) will be sent to the applicant if there are objections, since the WO-ISA from another office is not recognised as a WO-IPEA (unlike an EPO WO-ISA) and the Scope Annex does not legally qualify as a WO-IPEA (see <u>GL/PCT-EPO C-IV, 2.1</u>).

PCT - Part C

Guidelines for Procedural Aspects in Chapter II

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Chapter I – Introduction

1. General remark

Chapters <u>C-II</u> to <u>IX</u> set out the general procedure for the international preliminary examination under <u>PCT Chapter II</u>, together with guidance on particular matters where necessary. They do not provide detailed instructions on matters of internal administration.

Matters of substantive law, i.e. the requirements which a PCT application must fulfil, are dealt with in Parts F, G and H.

2. Work of an examiner

See ISPE Guidelines 3.05.

3. Purpose of international preliminary examination

While the search and the accompanying written opinion under <u>Chapter I</u> are mandatory for applicants, examination under <u>Chapter II</u> is optional.

For the usefulness of <u>PCT Chapter II</u> for the applicant, see the Euro-PCT Guide, points 297-301.

The end product of the PCT procedure is the international preliminary report on patentability (IPRP) <u>Chapter I</u> or <u>Chapter II</u>. This report will be the result:

Rules 44bis and 70

i. either of further examination under <u>Chapter II</u> (see below) in the form of an international preliminary examination report (IPER) from the International Preliminary Examining Authority

Rule 70 GL/ISPE 3.02

ii. or, if no demand under <u>Chapter II</u> is filed, of the International Bureau's conversion of the WO-ISA into an IPRP of the International Searching Authority, which is made public at 30 months from the priority date or shortly thereafter together with any informal comments submitted by the applicant. Such comments will be annexed to the report. Since no demand for preliminary examination under <u>Chapter II</u> has been filed, there is no re-examination of the WO-ISA.

Rule 44bis GL/ISPE 2.18

In its capacity as an International Preliminary Examining Authority (i.e. under <u>Chapter II of the PCT</u>), the EPO is empowered to carry out international preliminary examination (IPE), the objective of which is to formulate a preliminary and non-binding opinion on whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable. When appropriate an opinion will also be given on added subject-matter, unity, insufficient disclosure and clarity or support issues, as well as formal defects.

Article 33(1) GL/ISPE 19.02

The international preliminary examination does not lead to either a grant or a refusal of a patent; instead, at the end of the procedure, a report – the IPRP <u>Chapter II</u> or IPER – is established. The procedure under <u>Chapter II</u>

Rule 66 GL/ISPE 3.19 allows the applicant to submit amendments and arguments in response to the WO-ISA and, if applicable, to a WO-IPEA, which will be taken into account when establishing the report.

Art. 32 Rule 59 GL/ISPE 1.13-1.15 The EPO is a Preliminary Examining Authority for the vast majority of PCT contracting states. All applications are treated in the same manner irrespective of their country of origin.

November 2016 PCT-EPO Guidelines Part C – Chapter II-1

Chapter II – Formal requirements to be met before the start of the international preliminary examination

1. Filing of the demand

The demand for international preliminary examination must be made using the prescribed form (PCT/IPEA/401).

Art. 31(3) Rule 53

A demand for preliminary examination selecting the EPO as IPEA must be filed with the EPO in Munich, Berlin or The Hague, in writing, by hand, by post, by facsimile or electronically. The EPO will indicate the date of receipt on the demand and promptly notify the applicant of that date. If the demand is filed by fax, no written confirmation needs to be filed unless the applicant is invited by the EPO as IPEA to do so.

Art. 31(6)(a)
OJ EPO 2014, A71
Rule 92.4(e), (g)
OJ 2007, Spec. ed.3,
A.3 (Art. 3 and 7 of
the Decision)

If the applicant filed the demand incorrectly with the International Bureau (IB), a receiving Office, an International Searching Authority or a non-competent International Preliminary Examining Authority, that Office or Authority or the IB will mark the date of receipt and will transmit the demand to the EPO as IPEA.

Rule 59.3

The time limit for filing the demand for international preliminary examination with the EPO is as defined in Rule 54bis.1.

2. The EPO as competent IPEA

The IPEA receiving the demand should ensure that it is competent to act as IPEA.

Art. 31(6)(a) and 32, Rule 59.3

Although the EPO's competence as an IPEA is not restricted to international applications from EPC contracting states, restrictions of various nature limit its competence. Details are provided in the Euro PCT Guide, points 305-310.

In particular, the EPO is competent to act as IPEA only if the international search was carried out by the EPO or by the Austrian, Finnish, Spanish or Swedish patent office, the Nordic Patent Institute (NPI) or the Visegrad Patent Institute (VPI).

Agreement EPO-WIPO, <u>Art. 3(2)</u>, Annex A(ii) OJ 2010, 304 OJ 2014, A117

3. Identification of the international application in the demand

The international application must be identified by indicating the international application number, the international filing date, the title of the invention and the name and address of the applicant.

Rules 53.6 and 60.1(b)

4. Applicant's entitlement to file a demand

The demand should contain the name and the address (including postal code and name of the country) of the applicant, the state of nationality and the state of residence.

Art. 31(2), Rules 18.1 and 54

Sole applicants must have their residence in, or be a national of, a PCT contracting state bound by <u>PCT Chapter II</u>. If there is more than one applicant, at least one of the applicants has to fulfil these requirements. Secondly, the international application must have been filed with a receiving Office of or acting for a PCT contracting state bound by <u>PCT Chapter II</u>. See also Euro-PCT Guide, points 311-312.

5. Representation

Rule 90 Art. 31(2), Rule 54 The demand should indicate the agent or common representative who has been appointed by the applicant(s) or a sub-agent who has been appointed by an agent appointed under <u>Rule 90.1(a)</u> ("the agent for the international phase").

Where an agent is appointed, any correspondence intended for the applicant will be sent to the address indicated for the agent.

If there are two or more applicants and no common agent or common representative is appointed, all correspondence will be sent to the first-named applicant who has the right to file an international application with the receiving Office concerned, as he will be considered to be the common representative ("deemed common representative").

6. Election of states

Art. 37, Rule 53.7 GL/ISPE 22.11 The filing of the demand constitutes the election of all contracting states which are designated and are bound by <u>Chapter II</u> of the PCT.

7. Signature

Rules 53.8, 90.3(a), 90.4(a) and (b)

The demand must be signed either by the applicant(s) or by the (common) agent or the common representative.

8. Basis for international preliminary examination

Art. 19 and 34
PCT Applicant's
Guide Int. Phase,
Annex E
Rule 66

The preliminary examination is based on the international application either as filed or as amended under <u>Article 19</u> or <u>34</u> (see also <u>GL/PCT-EPO C-III</u>).

The applicant must indicate on which basis he wishes the IPEA to start the international preliminary examination – application as originally filed or with amendments (<u>Article 19</u> or <u>Article 34</u>), translations, comments about WO-ISA (indexed ISOREPLY) or about ISR, sequence listing in the language of the IPE.

Rule 58.1 and 58.3

Additionally, a fee for preliminary examination and a handling fee are to be paid (see <u>GL/PCT-EPO C-II, 11</u>).

9. IPEA file

Art. 39(1)(a)
PCT AI section 605

The EPO as IPEA promptly establishes the file when the conditions under Rule 69.1(a) are fulfilled, using the existing ISA file or creating a new file if the EPO was not the ISA.

10. Correction of deficiencies

Certain defects might be corrected *ex officio* by the IPEA; for others, the EPO as IPEA invites the applicant to correct the defects within one month of the date of the invitation. If the applicant complies with the time limit, the demand is deemed to have been received on the actual filing date, provided that the demand as submitted sufficiently identified the international application. If the applicant does not comply with the invitation in due time, the demand is deemed not to have been submitted.

Art. 31(3) Rules 53, 55 and 60 GL/ISPE 22.37-22.41

11. Payment and refund of fees

Both the preliminary examination fee and the handling fee must be received at the EPO as IPEA one month from the date of receipt of the demand or 22 months from the earliest priority date, whichever expires later. The preliminary examination fee is set by the EPO. The handling fee is provided for in the Schedule of Fees under the PCT which is published by the IB. The amounts of the handling fee and the preliminary examination fee to be paid are those applicable on the date of payment.

Rules 57 and 58 GL/ISPE 22.42-22.48

Both fees may be refunded in certain circumstances:

The preliminary examination fee:

Where the international application or the demand for international preliminary examination is withdrawn before examination has commenced and within 30 months from the priority date, the applicant is refunded 75% of the fee for international preliminary examination. If the demand is deemed not to have been submitted or the fee was paid by mistake, the fee is refunded in full. Any amount paid in excess of the amount due is likewise refunded (see also GL/PCT-EPO A-II, 4.2 and A-II, 5.2).

Rule 58.3 Agreement EPO-WIPO, Annex C-II OJ 2010, 304 OJ 2014, A117

The handling fee:

For the conditions for refunding the handling fee see Rule 57.4.

12. Transmission of demand to the International Bureau

The transmission of the demand to the International Bureau should be effected not later than one month after receipt of the demand.

Rules 61.1 and 90bis.4(a)

November 2016 PCT-EPO Guidelines Part C – Chapter III-1

Chapter III – Documents forming the basis of the international preliminary examination

1. Substitute sheets and rectified sheets

Replacement pages or sheets, filed in response to an invitation by the receiving Office to correct defects in the international application, are deemed to be part of the international application "as originally filed". These sheets are identified with a stamp "SUBSTITUTE SHEET (RULE 26)" (see GL/PCT-EPO H-IV, 1). Also, replacement pages or sheets for rectification of obvious mistakes under Rule 91 are deemed to be part of the international application "as originally filed". These sheets are identified with "RECTIFIED SHEET (RULE 91.1)" (see GL/PCT-EPO H-IV, 2.2).

Rule 26 Rule 91.1 GL/ISPE 17.16

See <u>GL/PCT-EPO H-IV, 2</u>, for the procedure to follow if the rectified sheets contain added subject-matter.

2. Sheets filed under Rule 20.6 containing missing parts

An applicant that has omitted to file parts of the application may still furnish them at a later date without affecting the international filing date, subject to the requirements of Rules 4.18 and 20.6(a) and provided the missing parts were completely contained in the priority document. The examiner checks whether the RO's assessment of the "completely contained" criterion was correct (see GL/PCT-EPO GL/PCT-EPO H-II, 2.2.2).

Rule 20.6

If these part(s) were indeed completely contained in the priority document (or if the priority document and any other document needed are not available), the examiner will treat the file as having the filing date accorded by the RO. If the documents needed for the check are not available, this will be indicated in the IPER, in Section I of the separate sheet.

If these part(s) were not completely contained in the priority document, the decision on the filing date made by the RO is still valid for the international phase. However, the examiner will indicate in the IPER under Section I on the separate sheet that there are doubts as to whether the missing part(s) were actually completely contained in the priority document. The IPER will also include documents which would be relevant if the application were to be redated (see also <u>GL/PCT-EPO B-III, 2.3.3</u>).

3. Amended sheets

Any change, other than the rectification of obvious mistakes in the claims, the description or the drawings is considered an amendment. Unless withdrawn or superseded by later amendments, any change considered an amendment must be taken into consideration for the purpose of the international preliminary examination.

Art. 19 Art. 34(2)(b) Rule 66.5 GL/ISPE 20.04

See <u>GL/PCT-EPO H-II</u> and <u>H-III</u> for details.

4. Added subject-matter

All amended pages (description, claims, drawings) must be examined to see whether they introduce subject-matter not originally disclosed. The GL/ISPE 20.09

same criteria should be used as under <u>Art. 123(2) EPC</u> for the European procedure (see <u>GL/PCT-EPO H-II</u> and <u>III</u>).

Concerning the applicant's obligation to indicate the basis for the amendments in the application as originally filed, see <u>GL/PCT-EPO H-I, 6</u>.

Art. 19(2) Art. 34(2)(b) Rule 70.2(c) If any newly filed claim, drawing or part of the description contains amendments which are considered to go beyond the disclosure as originally filed, the claim concerned is examined, taking into consideration only those technical features which have a basis in the application as originally filed, disregarding the amendments which are considered as introducing added subject-matter.

If that is not possible, the text of the claims as originally filed or amended under Art. 19(1) is examined and this information is entered on the cover sheet and in Section I of the WO-IPEA (Form 408) and/or of the IPER (Form 409). On the separate sheet, reasons must be given as to why the amendments introduce subject-matter not originally disclosed and why they are disregarded.

November 2016 PCT-EPO Guidelines Part C – Chapter IV-1

Chapter IV – Examination of the WO-ISA and replies

1. General procedure

Under <u>Chapter II</u>, the reply to the WO-ISA, WO-IPEA (Form 408) or telephone minutes with possible amendments will be examined.

The final result of this examination under <u>Chapter II</u> is the issuance of the IPER (see <u>GL/PCT-EPO C-VIII</u>).

The examiner will first consider whether the objections raised in the WO-ISA have been overcome by the submitted arguments and/or amendments. If this is the case the IPER will be issued directly provided that the top-up search does not yield any pertinent prior art (see <u>GL/PCT-EPO C-IV, 5.4</u>). If objections have not been overcome or if pertinent prior art is found in the top-up search (see <u>GL/PCT-EPO C-IV, 5.3</u> and <u>5.4</u>), a further WO-IPEA or telephone minutes should be issued as set out in <u>GL/PCT-EPO C-IV, 2.2</u>.

If a further WO-IPEA or telephone minutes setting a time limit for reply are issued, the examiner will examine any reply from the applicant and will then as a rule draft the IPER directly even if objections still occur, unless there is an outstanding request for a telephone consultation (see <u>GL/PCT-EPO C-IV, 2.2</u>, and <u>C-VII, 1</u>). An exception could be if it is clear that minor amendments could be suggested during e.g. a short telephone consultation which would result in a positive IPER, so that it would appear procedurally expedient to solve these problems in the <u>Chapter II</u> phase.

OJ EPO 2011, 532

2. Dispatch of a further written opinion (Form 408)

2.1 Procedure when the EPO was not the ISA

Where the ISR and WO-ISA were established by another European International Searching Authority (at present SE, ES, AT, FI, NPI (XN) and VPI (XV)), the WO-ISA is not considered as the first written opinion for the procedure under <u>Chapter II PCT</u> and the examiner will examine the file, taking into account the WO-ISA and any reply from the applicant on file. If there are objections as to novelty, inventive step and/or industrial applicability, he will send a WO-IPEA with a time limit for the applicant to reply as laid down in <u>Rule 66.2(d)</u>, which is normally two months.

Rule 66.1bis

GL/ISPE 3.19

If, despite the applicant's timely and substantive reply (in the form of amendments and/or arguments) to this WO-IPEA, there are still objections outstanding, possibly resulting from the top-up search in <u>Chapter II</u> (see <u>GL/PCT-EPO C-IV, 5</u>), a further written opinion or telephone minutes are issued as set out under <u>GL/PCT-EPO C-IV, 2.2</u>.

2.2 Procedure when the EPO was the ISA

The applicant must be given a further opportunity for interaction in Chapter II before a negative IPER is established, on condition that he has

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filed in due time a substantive reply to the WO-ISA in the form of amendments and/or arguments.

Thus if, after reply to the WO-ISA, there are still objections outstanding, before issuing a negative IPER the examiner must send:

- as a rule, a (further) written opinion (Form 408, WO-IPEA), but:
- if a request for a telephone consultation was filed before the (further) written opinion was issued: telephone minutes;
- if a request for either a telephone consultation or a (further) written opinion (see <u>GL/PCT-EPO_C-VII, 1</u>) was filed before the (further) written opinion was issued: a written opinion or telephone minutes,

Rule 66.2(d)

in either case generally (see <u>GL/PCT-EPO C-VII. 1</u>) with a time limit to reply which is normally two months, in order to give the applicant a further opportunity to provide arguments and/or amendments in reply to any outstanding objections. Documents newly found during the top-up search (see <u>GL/PCT-EPO C-IV, 5</u>) are attached to the WO-IPEA or to the telephone minutes, as appropriate.

If the applicant has not submitted any response to the WO-ISA with his demand, and the top-up search in <u>Chapter II</u> does not reveal any new pertinent prior art, then a negative IPER, repeating the objections raised in the WO-ISA, will be issued directly.

In the exceptional situation of a non-unitary application, where all inventions examined were found novel and inventive, but still lacking unity as the only remaining objection, a negative IPER can be sent directly without a further WO-IPEA (see GL/PCT-EPO C-VIII, 3).

2.3 Supplementary international search (SIS) by another office

When conducting preliminary examination under <u>Chapter II</u>, the examiner must also take into account any documents cited in any supplementary international search report (SISR) by another office which is available in the file.

If the SISR has not been received by the EPO 24 months after the priority date, the file will be sent to the examiner anyway. If, after checking, the examiner concludes that an invitation to pay additional fees in case of lack of unity (see <u>GL/PCT-EPO C-V, 1</u>) or a WO-IPEA (see <u>GL/PCT-EPO C-IV, 2.2</u>) has to be sent, he will do so as soon as possible without awaiting the SISR.

If neither an invitation to pay additional fees in case of lack of unity nor a WO-IPEA needs to be sent out before the IPER is established, the examiner waits until 27 months from the priority date to establish the IPER to allow the SISR to arrive and be taken into account.

If the IPER has not yet been established, the examiner will take the SISR into account when establishing the IPER.

Rule 45bis.8(c)

2.4 Files arriving late

If the demand has been validly received by the EPO very late, the examiner will telephone the applicant and explain the situation. The applicant will then be asked whether he prefers to:

- discuss the application over the phone and receive a short time limit to file amendments (e.g. one to two weeks, set by the telephone minutes); or
- receive a WO-IPEA with a short time limit (e.g. one to two weeks); or
- receive a negative IPER without further interaction; or
- receive a WO-IPEA with a longer time limit, in which case the IPER will be issued late.

In the very exceptional case that the file is so late that even with a time limit of one to two weeks the IPER would be issued after 28 months, the applicant will be asked whether he still wishes a time limit to file amendments although the IPER will be late or prefers a timely but negative IPER without further interaction.

In the above-mentioned exceptional cases where after a telephone consultation the applicant does not wish to file amendments/observations but agrees that a negative IPER can be established directly, the examiner will send a direct negative IPER.

2.5 Request for a further written opinion

Frequently applicants explicitly ask for a further written opinion (under <u>Chapter II</u>) if the examiner's opinion is still negative. If the applicant has not yet had a further opportunity to file amendments in <u>Chapter II</u>, his request must be granted (see <u>GL/PCT-EPO C-IV, 2.2</u>).

If the applicant has already had a further opportunity to file amendments, then as a rule the IPER is issued directly (see however also <u>GL/PCT-EPO</u> <u>C-IV, 1</u>).

3. Late-filed reply after a first or further WO-IPEA (408) has been sent In the PCT procedure, there is no loss of right for the applicant if he does not meet the time limits for replying to a written opinion. The only risk the applicant takes with a late reply is that it might not be taken into account for establishing the IPER.

Rule 66.4bis GL/ISPE 19.32

In practice, if the applicant's reply is received after the time limit set in the WO-IPEA (Form 408) but before an IPER (Form 409) has been started, the late-filed reply is taken into consideration for drawing up the IPER.

GL/ISPE 19.33

If a reply is received after the IPER has actually been started and the applicant has not met all the objections set out in the last written opinion, the late reply is not considered and the IPER is drawn up on the basis of the conclusions set out in the last WO-IPEA.

If a reply is received after the IPER has actually been started and all the objections set out in the last WO-IPEA have been met, the late-filed reply is taken into consideration for drawing up the IPER.

If no reply has been received, the IPER is drawn up on the basis of the conclusions set out in the last WO-IPEA.

4. Consequences of a restriction of the search

4.1 Submissions prompted by a restriction of the search or a declaration that no search is possible

Rule 66.1(e)

If the search covered only some claims or part of one or more claims (see <u>GL/PCT-EPO B-VIII</u>), only the subject-matter which has been searched - as indicated in the ISR (<u>GL/PCT-EPO B-X, 8</u>) and/or in the WO-ISA (<u>GL/PCT-EPO B-XI, 6</u>) - can be the object of the international preliminary examination. It should always be made clear which claims have been examined.

Art. 17(2)(a)(i) and (ii)

After a restriction of the search, either because subject-matter is excluded from the search or because a meaningful search is not possible, or after a declaration that no search at all is possible, the examiner at subsequent stages of the procedure may be confronted with arguments from the applicant that he disagrees with the findings of the ISA.

However, the IPEA has no responsibility for actions taken by the ISA, and there is no provision in the PCT for an IPEA review of, or for an appeal against, such an ISA decision.

Any written arguments from the applicant relating to the completeness of the search are not to be treated as a communication with the IPEA, and the formalities officer will issue a standard letter in reply, unless the applicant's reply contains a complaint against the findings at the search stage when the EPO acted as ISA (see GL/PCT-EPO C-IX, 4).

If the reply to the WO-ISA contains arguments challenging the findings at the search stage related to the restriction of the search, the examiner will additionally indicate in the IPER (under Section III) that the findings of the ISA cannot be reviewed by the IPEA.

Rule 66.1(e)

The applicant may attempt to contact the examiner by telephone to discuss the issue orally. In such cases, the examiner will inform the applicant that this is a matter which is the responsibility of the ISA under <u>Chapter I of the PCT</u> and that the procedure before the ISA is closed.

If the reply contains amended claims introducing unsearched matter, the applicant will be informed in the IPER (under Section III) that an opinion cannot be given for unsearched matter.

4.2 Consequences of a declaration of no search or an incomplete search in subsequent European procedure

For unsearched subject-matter, no written opinion is established under <u>PCT Chapter II</u>. Chapter I and no examination is carried out under <u>PCT Chapter II</u>. Furthermore, there is no possibility for the applicant to appeal the decision of the ISA (see <u>GL/PCT-EPO C-IV, 4.1</u>), so that even if he were to succeed in convincing the examiner under <u>Chapter II</u> that the decision not to search certain subject-matter was incorrect, this has no consequences. However, in the European procedure the examining division must review the decision of the search division (examiner) and take a final decision. This implies that in the European phase for the Euro-PCT application the examiner might have to reverse the decision of the ISA and perform a complete search (either because of the arguments filed or because of the claims having been redrafted so that a search can now be performed, see also <u>GL/EPO C-IV, 7.2</u>).

5. Top-up searches in PCT Chapter II

A top-up search is mandatory at the outset of <u>PCT Chapter II</u>, subject to some exceptions. The date - or absence - of this top-up search must be indicated in the IPER.

Rules 66.1ter and Rule 70.2(f) GL/ISPE 19.15, 19.19-19.20

5.1 Timing, basis and forms

The top-up search will be conducted before/at the same time as issuing the first WO-IPEA (Form 408)/telephone consultation or, where no written opinion is produced, the IPER (Form 409) (approximately 23 months from the priority date). A further top-up search before issuance of the IPER is normally not necessary.

GL/ISPE 19.18

In the case of non-unity where there is more than one invention claimed for which examination under <u>Chapter II</u> is demanded, the examiner will first issue an invitation to pay additional examination fees (Form 405) and then perform the top-up search for all inventions for which additional examination fees have been paid.

Art. 34(3)(a) GL/ISPE 19.16

The IPEA must indicate in the IPER whether or not a top-up search has been done. The date indicated in the form is the date of the latest top-up search. The box which indicates that no top-up search has been done is only ticked if all the claims are exempted from top-up search.

Rule 70.2(f)

5.2 Exemptions from top-up search

As a general rule, a top-up search will be conducted for all the claims forming the basis for the <u>Chapter II</u> examination, as indicated in boxes I and III of the WO/IPER.

GL/ISPE 19.15

A top-up search is not conducted on:

Rule 66.1ter

(a) subject-matter not searched by the ISA;

Rule 66.1(e)

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Art. 34(3)	(b)	non-unity cases - inventions for which additional sepaid, but not additional examination fees;	earch fees were	
<u>Art. 34(4)</u>	(c)	subject-matter which, although not excluded from the searce excluded from preliminary examination;		
		ddition to what is mentioned in <u>Rule 66.1<i>ter</i> PCT, the</u> be refused or limited by the EPO as IPEA:	e top-up search	
Art. 34(2)(b) and	(d)	where amendments contain added matter;		
19(2) GL/ISPE 19.17 Rule 46.5(b) and 66.8	(e)	where there is no letter explaining the basis for amount indicating what has been amended in the application		
	(f)	where the EPO as ISA would not cite any document to the relevant state of the art (e.g. in case of "notor in the field of computer-implemented inventions).	•	
Rule 70.2(c)	In case (d) above, the examiner will perform the top-up search base either the previous set of application documents or the amended ignoring the added subject-matter. In case (e) above, the same application unsupported amendments (see <u>GL/PCT-EPO C-III, 4</u>).			
		Where a top-up search is made for some claims or part of claims, there i no indication of:		
	_	which claims are not covered by the top-up search derivable from the indications in Sections I and III o or	•	
	-	why no or only a partial top-up search has been mad	e.	
	5.3	Documents newly found in the top-up search, who	en further	
GL/ISPE 3.22	If the a W (see object	ctions are present top-up search reveals pertinent prior art, according to O-IPEA or a telephone consultation is the first action GL/PCT EPO C IV, 2.2). If a positive WO-ISA was actions in the negative WO-ISA have been overcome by andments/arguments, see GL/PCT-EPO C IV, 5.4.	on in <u>Chapter II</u> drafted or the	
GL/ISPE 19.21	The documents found are indicated as follows:			
Rule 64.3	(a)	If the newly found documents are published afte (E documents) and are relevant for novelty, they a Section VI of the WO-IPEA and IPER (for the lever GL/PCT-EPO B-XI, 4.3).	re mentioned in	
Rule 64.1	(b)	If the newly found documents are published before and are relevant for novelty and/or inventive mentioned in Section V of the WO-IPEA and IPE	step, they are	

reasoning is provided.

- (c) If the newly found documents are published in the priority period (P documents) and are relevant for novelty and/or inventive step, and if the priority is (assumed to be) valid, the documents are mentioned in Section VI of the WO-IPEA and IPER; comments are optional (see GL/PCT-EPO B-XI. 4.2). This applies only if there are other objections; otherwise, see GL/PCT-EPO C-IV, 5.4.
- (d) If the newly found documents are published in the priority period (P documents) and are relevant for novelty and/or inventive step, and if the priority is invalid, the documents are mentioned in Section V of the WO-IPEA and IPER and detailed reasoning is provided.

Documents found during the top-up search and mentioned in the WO-IPEA will also be mentioned in the IPER, unless rendered irrelevant by amendments or arguments provided by the applicant during the international preliminary examination. It will be always indicated in Box I of the IPER that additional relevant documents were found during the top-up search.

5.4 Intended positive IPER and top-up search

If a positive WO-ISA was drafted or the objections in the negative WO-ISA have been overcome by the applicant's amendments/arguments, and if the top-up search reveals:

- (a) no relevant documents, a positive IPER is issued directly.
- (b) pertinent prior art published before the priority date, a WO-IPEA or telephone minutes is/are issued (GL/PCT-EPO C-IV, 2.2). Details of how the document is indicated can be found in GL/PCT-EPO C-IV, 5.3(b).

Rule 64.1

- (c) only P/E documents which are (could become) prior art under Art. 54(3) EPC in later EP proceedings (independently of the validity of the priority), a WO-IPEA with detailed novelty reasoning is sent (GL/PCT-EPO B-XI, 3.4); the document is introduced in Section VI and its possible relevance upon entry into the EP phase is indicated. Details of how the document is indicated can be found in GL/PCT-EPO C-IV, 5.3(a).
- (d) other P/E documents relevant for novelty and if the priority is (assumed to be) valid, a positive IPER is sent directly (GL/PCT-EPO B-XI, 3.4), and the document is mentioned in Section VI of the IPER.

Chapter V - Unity of invention

1. Unity of invention under Chapter II

If an invitation to pay additional fees was issued during <u>Chapter I</u> and the applicant paid some or all of the required additional fees, and if, where applicable, the objection as to lack of unity was at least partly upheld during a protest procedure, then under <u>Chapter II</u> the applicant will normally be invited (using Form 405) to pay additional examination fees if all the searched inventions are also to be examined under <u>Chapter II</u>. Inventions for which no search fees were paid cannot be pursued and will thus also not be objected to or commented on. A review of the decision taken under <u>Chapter I</u> is not provided for in the PCT.

Art. 34(3)(a)-(c) Rule 68.2 GL/ISPE 10.74

A single WO-IPEA/IPER is then drafted by the examiner, dealing with all the inventions for which examination fees have been paid.

In reply to the WO-ISA the applicant may have filed redrafted claims which differ substantially from those for which lack of unity was raised. In such a case it should be carefully considered whether:

- the lack of unity objection still applies to the new set of claims
- the amended claims relate to searched subject-matter
- the reasoning as to lack of unity has to be amended because of the new claims and/or the arguments presented.

Normally, the examiner under <u>Chapter II</u> agrees with the objection made at the search stage. Exceptionally, if this is not the case (e.g. if the search and WO-ISA were made by another office), it is possible to send out an invitation to pay further examination fees (Form 405) even if this was not done at the search stage. However, if a lack of unity objection was raised at the search stage resulting in a partial search and a different conclusion is reached under <u>Chapter II</u>, there is no possibility to ask for an additional search for unsearched subject-matter. In this case, examination in <u>Chapter II</u> is restricted to what has been searched.

Furthermore, it is possible that the original claims did not lack unity but the amended claims do. In such a case, if the amended claims lacking unity relate to unsearched subject-matter, they are not examined, and a WO-IPEA/IPER is established on searched subject-matter only (no Form 405 is to be sent out). On the other hand, if e.g. the applicant has generalised the original independent claim so that it is no longer novel and lack of unity a posteriori occurs, then an invitation to pay additional fees is sent before the WO-IPEA/IPER.

For information on the exceptional situation of a non-unitary application, where all inventions examined were found novel and inventive, but still lacking unity as the only remaining objection, see <u>GL/PCT-EPO C-VIII, 3</u>.

2. No payment of additional search fees

If, in reply to the objection to lack of unity at the search stage, the applicant has not paid additional search fees, the WO-IPEA/IPER is based on the claims for which the search report and the WO-ISA have been drafted, taking amendments and arguments from the applicant into account. Section IV is not filled out.

3. Searched claims did not comply with unity of invention

3.1 Payment of additional search fees without protest

If, in reply to the objection to lack of unity at the search stage, the applicant has paid additional search fees without protest, and the application still lacks unity, the objection indicated on Form 206 and in the WO-ISA will normally be confirmed, where necessary adapted to the amendments/arguments filed by the applicant.

Art. 34(3)(a) Rule 68.2 Form 405 is sent out, requesting additional examination fees only for those inventions which have been searched and which are still present in the claims.

3.2 Payment of additional search fees under protest

Rule 68.3(c) GL/ISPE 10.78 If, in reply to the objection to lack of unity at the search stage, the applicant has paid additional search fees under protest and

- (a) the Review Panel decided that the protest was fully justified, no invitation to pay additional fees (Form 405) is sent. The Review Panel's decision is followed and the WO-IPEA/IPER is established for all searched inventions;
- (b) the Review Panel decided that the protest was partly justified, an invitation to pay additional fees (Form 405) is sent, with the reasoning and the number of inventions adapted to the Review Panel's decision.

The examiner should ensure that the lack of unity objection raised at the search stage is still valid for the newly filed claims.

3.3 No request for payment of additional search fees

Rule 68.1 GL/ISPE 10.76 If, at the search stage, an objection of lack of unity was raised but exceptionally it was chosen not to request the applicant to pay additional search fees, the examination is carried out on the entire application. No invitation to pay additional fees (Form 405) is sent; instead, the WO-IPEA/IPER is established for all searched inventions. Under Section IV, it is indicated that the requirement of unity is not fulfilled.

4. Applicant's reply to the invitation to pay additional fees (Form 405)

4.1 No payment of additional examination fees or failure to reply

If, in reply to the invitation in Form 405, the applicant neither restricts the claims nor pays additional examination fees, or if the applicant does not reply, the WO-IPEA/IPER is established on the basis of the main or first invention mentioned in the invitation to pay additional fees (Form 405) and for which the search fee has been paid. Section IV is filled out and the reasons for lack of unity are given on the separate sheet.

Art. 34(3)(c) Rule 68.4-68.5 GL/ISPE 10.75

If, in reply to the invitation in Form 405, the applicant restricted the claims, the examiner has to check whether the restricted set of claims is unitary and whether all claims relate to searched subject-matter.

If this is the case, the WO-IPEA/IPER is established on the restricted set of claims, and Section IV is not filled out.

If this is not the case, the WO-IPEA/IPER is established on the main or first invention mentioned in Form 405 and for which the search fee has been paid; Section IV is filled out, and any claims relating to non-searched subject-matter are indicated in Section III.

4.2 Payment of additional examination fees without protest

If, in reply to the invitation in Form 405, the applicant pays additional preliminary examination fees without protest, the WO-IPEA/IPER is established on the basis of those inventions for which examination fees have been paid. Section IV is filled out and the reasons for lack of unity are given on the separate sheet.

If, in reply to the invitation in Form 405, the applicant restricted the claims and paid additional fees, the examiner has to verify that the restricted set of claims does not contain more inventions than those for which additional fees have been paid and that the restricted claims relate to subject-matter that has been searched.

If this is the case, the WO-IPEA/IPER is established on the restricted set of claims, and Section IV is filled out.

If this is not the case, the WO-IPEA/IPER is established on as many inventions mentioned in Form 405 as additional fees have been paid for. Section IV is filled out and any claims relating to unsearched subject-matter are indicated in Section III.

In both cases the reasons for the lack of unity are given on the separate sheet.

4.3 Payment of additional examination fees under protest

In reply to Form 405, the applicant may pay some or all of the additional fees under protest. If he does, then this triggers the protest procedure for

Rule 68.3(c) and (e) GL/ISPE 10.78 determining whether the request for payment of the additional fees was justified (see also GL/PCT-EPO C-V, 5).

5. Protest procedure

Rule 68.3(c), (d)

The protest procedure consists of a review within the IPEA first by the formalities officer and then by a Review Panel.

5.1 Admissibility of the protest

Rule 68.3(c), (e) GL/ISPE 10.79 Before initiating the protest procedure the formal admissibility of the protest in the sense of <u>Rule 68.3(c)</u> (<u>Chapter II</u>) must be checked.

To be admissible the protest should satisfy the following requirements:

- (a) The applicant must have paid the prescribed protest fee (Rule 68.3(e)), and
- (b) The payment under protest must be accompanied by a reasoned statement, i.e. the reasoned statement should have been filed with the payment or at the latest within the time limit set in Form 405 (Chapter II).

The reasoned statement must comply with <u>Rule 68.3(c)</u>; i.e. the applicant should argue why the international application complies with the requirement of unity of invention or why the amount of the required additional fee is excessive. In the protest the applicant should question the number of additional examination fees that he has been invited to pay, and not the amount of a single additional fee.

The payment of the protest fee and the presence of a reasoned statement are assessed by specially trained formalities officers. Any substantive analysis is made by the Review Panel when assessing the justification of the protest.

5.2 Review Panel

GL/ISPE 10.80

For the composition and purpose of the Review Panel, see <u>GL/PCT-EPO</u> <u>B-VII, 7.2</u>. The names of the members of the Review Panel are made public on Form 420.

The scope of the review is limited to those inventions for which additional fees have been paid. If the applicant's reasoning is not related to those inventions, the Review Panel will come to the conclusion that the protest is not or is only partially justified, depending on the case.

GL/ISPE 10.81

If the Review Panel determines that the protest is wholly justified, it will inform the applicant with Form 420 (Decision on Protest <u>Chapter II</u>). This also applies if the Review Panel's finding results in the application not lacking unity. It is not necessary to give any reasoning unless the Review Panel decides that such reasoning would be beneficial. Furthermore, the Review Panel will order the reimbursement of all the additional fees and the protest fee. The examination will be carried out on the inventions for which the fees are paid, and the non-unity reasoning and the number of

inventions in the IPER (or WO-IPEA) will be adapted to the Review Panel's decision.

If the Review Panel considers that the protest is not justified at all, it will communicate this to the applicant with Form 420. Reasoning must be given indicating why the request for payment of the additional fees is upheld. The examination will be carried out on the inventions for which the fees are paid.

If the Review Panel considers that the protest is only partially justified, it will communicate this to the applicant with Form 420. Reasoning must be given indicating why the request for payment of the additional fees is partially upheld. The examination will be carried out on the inventions for which the fees are paid, and the non-unity reasoning and the number of inventions in the IPER (or WO-IPEA) will be adapted to the Review Panel's decision. The Review Panel will order the reimbursement of the corresponding additional fees but not the protest fee.

The formalities officer will send the decision of the Review Panel to the applicant and the IB. The decision on protest (Form 420) will be sent out together with the WO-IPEA or IPER in order to ensure that both are consistent.

GL/ISPE 10.82

Chapter VI – Time limits

1. Start of the international preliminary examination

The EPO as IPEA will not start the international preliminary examination before expiry of the time limit laid down in <u>Rule 54bis</u>, unless the applicant requires an earlier start.

Rule 69.1(a) Rule 54bis.1(a) GL/ISPE 19.07

Amendments and/or arguments under <u>Article 34</u> filed after filing of the demand, but before the expiry of this time limit, will always be taken into account for international preliminary examination.

Rule 66.4bis

The EPO as IPEA does not apply <u>Rules 69.1(b)</u> and <u>69.1(b-bis)</u>, i.e. it will not start the international preliminary examination at the same time as the international search.

Rule 69.1(b), 69.1(b-bis)

2. Time limit for international preliminary examination

The time limit for establishing the international preliminary examination report is laid down in <u>Rule 69.2</u>. Where the documents required for the preliminary examination were received in due time, the EPO will establish the IPER within 28 months from the priority date.

Rule 69.2(i) GL/ISPE 3.24, 19.10

The applicant has a time limit of 31 months from the priority date to enter the European phase before the EPO.

Rule 159(1) EPC Art. 22(1), (3) Art. 39(1)(a), (b)

3. Extension of the time limit

Failure to meet the time limit set in the WO-ISA or the WO-IPEA does not constitute a formal loss of rights; see <u>GL/PCT-EPO C-IV, 3</u>.

Requests for extension of the time limit for replying to the WO-ISA where it is considered as a first opinion of the IPEA are handled by the formalities officers. As a rule, a one-month extension will be granted if requested before expiry of the normal time limit under <u>Rule 54bis</u> and on condition that the time limit so extended does not expire later than 25 months from the (earliest) priority date; further extensions are not allowed. The extension does not apply to the time limit for filing the demand, which cannot be extended.

A request for extension of the time limit to reply to a WO-IPEA (Form 408) will be granted only if there is sufficient time available to grant the extension in view of the time limit laid down in <u>Rule 69.2(i)</u>, i.e. if the extended time limit does not expire later than 27 months from the earliest priority date and the request is made prior to expiry of the set time limit.

Rule 66.2(e)

If the ISR was delayed so that the time limit of 28 months for establishing the IPER cannot be met, the request for extension should be granted.

Chapter VII - Other procedures in examination

1. Request for an interview or telephone consultation

Art. 34(2) gives the applicant the right to communicate orally with the IPEA. Thus, requests for telephone calls from applicants or agents (including those overseas) should be granted, but only after a written response to the WO-ISA and if applicable to an invitation to pay additional fees (Form 405) (in the case of lack of unity) has been filed. Requests for personal interviews are not granted. However, if an applicant requests a personal interview, the examiner should contact him by phone to inform him that it is the EPO's policy not to grant personal interviews, but that the matter can be discussed in the form of a telephone consultation.

Art. 34(2) Rule 66.6 GL/ISPE 19.41-19.46

If the applicant has requested a telephone consultation the following applies:

OJ EPO 2011, 532

- as a general rule the applicant has, upon request, the right to one telephone consultation;
- Rule 66.6
- after a telephone consultation the applicant should in general* be given a time limit (normally two months) to file amended claims and/or arguments;
- if, before issuance of the (further) written opinion (Form 408), the applicant has requested a telephone consultation or alternatively a further written opinion, the examiner has the discretion to decide which kind of interaction is most suitable for the application in question;
- in the specific case of a telephone consultation being requested after issuance of the further written opinion but before the date on which the IPER is established, the request must be granted before a negative IPER is issued. However, in this case the applicant does not have the right to file further amendments, unless an agreement has been explicitly reached (see below).

Rule 66.6

* If the applicant in a telephone consultation has expressed his intention not to file further observations/amendments and has agreed to a negative IPER without further interaction, minutes of a telephone consultation without a time limit are sent, directly followed by a negative IPER.

When a telephone consultation is arranged, the matters for discussion should be clearly stated in advance. If the arrangement is made by telephone, the examiner should record the particulars and briefly indicate in the file (Form 428: minutes of telephone conversation) the matters to be discussed as well as the date and time for the consultation. A copy of the arrangements recorded is sent to the applicant.

GL/ISPE 19.45

If the applicant wishes to discuss amended claims during a telephone consultation, a copy of such claims should be sent in advance to the

examiner in order to enable appropriate preparation. The time limit for such submissions will be set by the examiner on the record of the arrangement.

GL/ISPE 19.46

The result of the telephone consultation is recorded by the examiner and added to the file. The recording will depend upon the nature of the matters under discussion and will be forwarded to the applicant.

If the consultation replaces the second written opinion or takes place after a reply to a second written opinion but has ended with an agreement on amendments, Form 428 will include:

- a warning that the amendments cannot be made by the IPEA and
- an invitation for the applicant to file amended sheets normally within one month, but at least one month before the deadline for the IPER (unless as agreed with respect to the late issue of the IPER).

If the consultation takes place after a reply to a second written opinion and no agreement has been reached, the applicant is informed that his arguments will be taken into account when establishing the IPER.

2. Confidentiality

Art. 38 Rule 94.2 GL/ISPE 3.26 According to <u>Art. 38</u>, the international preliminary examination is confidential. This means that, for example, the written opinions are not open to public inspection until establishment of the IPER.

3. Examination of observations by third parties

For details on third-party observations please refer to GL/PCT-EPO E-I.

GL/ISPE 17.69

For relevant third-party observations in **Chapter II** the following applies:

- (a) If a negative IPER is envisaged and a second written opinion has not been sent, a WO-IPEA (Form 408) is drafted taking into account the third-party observations and the applicant's comments where available, and referring to the new prior-art documents in section V (see also GL/PCT-EPO C-IV, 2.2).
- (b) If the IPER would have been negative even without the third-party observations and a WO-IPEA has already been sent before receipt of these observations, no further written opinion is sent before establishment of the IPER.
- (c) If a WO-IPEA has already been sent before receipt of the third-party observations and the IPER would have been positive without the third-party observations, a new WO-IPEA is issued or the applicant is called, whichever course of action is considered the more expedient, in particular in the light of the deadline for issuing the IPER.

In cases (b) and (c) above, the IPER is established taking into account the third-party observations and the applicant's comments, and referring to the new documents where appropriate in Section V of the IPER.

(d) If a positive IPER is envisaged since, even though the third-party observations may refer to more relevant documents than the ones on file, they do not prejudice novelty and inventive step, the newly cited relevant documents are dealt with in the reasons in favour of patentability in Section V on the separate sheet as appropriate.

If the documents are relevant but do not add anything to what was already available, it is left to the examiner's discretion whether they need to be quoted in the IPER. For example, if the documents are a better starting point for the problem-solution approach, the examiner may wish to review his argumentation in support of the positive assessment of inventive step.

Third-party observations which are not relevant or not sufficiently understandable (see <u>GL/PCT-EPO E-I</u> for observations not in an EPO official language) do not need to be dealt with substantially in the WO-IPEA and/or in the IPER. A comment is included in Section V of the WO-IPEA and/or in the IPER indicating that the third-party observations have been taken into account and found not to be relevant or that the third-party observations could not be taken into account and why.

Chapter VIII - The IPER

1. Opinion given in the IPER (Form 409)

Art. 35(2) specifies that the report shall not contain any statement on the question of whether the claimed invention is or seems to be patentable or unpatentable according to any national law. Moreover, the purpose of the preliminary examination is merely to give an opinion, but it does not lead to a grant or a refusal of the application. In these circumstances, therefore, the report should not give the impression that any part of the application may or may not be allowable. It will only state whether or not the claims meet certain criteria.

Art. 35(2) GL/ISPE 19.48

2. Completing the IPER

The IPER is drafted in the same way as the WO-ISA, i.e. a positive or negative opinion will be given for all claims, taking into account the arguments and/or amendments submitted by the applicant.

Therefore, the same criteria apply to the IPER as to the WO-ISA with respect to all examination issues (see also GL/PCT-EPO B-XI).

In particular the IPER will only be established for claims which have been searched (as indicated in the WO-ISA); any amended claims that are directed to subject-matter not searched will not be considered and an indication will be made in Section III of the IPER (non-establishment of opinion), with reasons given on the separate sheet.

Rule 66.1(e) GL/ISPE 19.25

If no reply has been received to a written opinion or the objections raised in a previous written opinion are still valid, the comments contained in that written opinion can be transferred to the corresponding section in the IPER. However, if the applicant has submitted arguments in favour of the claims, then even if the objections previously raised are still valid, the examiner should, in a neutral way (i.e. without direct reference to the letter of reply in the sense of "see reply/arguments from the applicant"), deal with at least the main arguments from the applicant in order to ensure that the applicant knows that his arguments have been considered.

If arguments, facts and evidence, such as the results of a comparative test, produced by an applicant in response to a written opinion are of crucial importance in assessing inventive step, the examiner may base the argumentation in the IPER on the applicant's response. This is of importance to other offices which need to know why a particular conclusion has been reached. However, since the IPER should be written in a neutral way and should be self-contained, the examiner should not append to the IPER portions of the applicant's reply or refer directly to the applicant's letter of reply.

Rule 5.2 Rule 13ter.2 Rule 66.1(e) OJ EPO 2011, 372 OJ EPO 2013, 542 GL/ISPE 9.39, 15.12, 15.13 and 17.37

2.1 Sequence listings

Where no (complete) international search was carried out because the applicant did not file an electronic sequence listing conforming to WIPO Standard ST.25 in response to a request from the ISA or did not pay the late furnishing fee, the IPER will indicate under Section III that the examination is limited according to Rule 13ter.2 to the same extent as the search was limited because the applicant failed to comply with Rule 5.2 (no sequence listing) and/or Rule 13ter.1(a) (no computer-readable sequence listing). The examiner also indicates in Section III of the IPER that the examination is also limited according to Rule 66.1(e) because the search was incomplete.

Where a sequence listing in electronic form and compliant with WIPO Standard ST.25 is not available to the EPO as IPEA, the applicant may be invited to furnish such a sequence listing under <u>Rule 13ter.1(a)</u> and to pay the late furnishing fee under <u>Rule 13ter.1(c)</u> within a non-extendable period of one month from the date of the invitation.

3. Positive or negative IPER

As for the WO-ISA, the examiner needs to indicate whether the IPER is to be considered positive or negative. The same criteria apply as in GL/PCT-EPO B-XI, 3.4.

In the special case of a non-unitary application, where all inventions examined (normally after issuance of an invitation to pay additional fees (Form 405); see <u>GL/PCT-EPO C-V, 1</u>) were found novel and inventive, but still lacking unity - as the only remaining objection - the IPER is marked as negative. Under Section V, a positive statement as to novelty and inventive step is given for all examined inventions, and the objection as to lack of unity is reasoned under Section IV.

In this special case, the negative IPER can be sent directly without any further written opinion, as an exception to the general principle outlined in <u>GL/PCT-EPO C-IV, 2.2</u>, that prior to issuing a negative IPER a WO-IPEA (Form 408) is to be sent. The reason for this exception is that the applicant is entitled to have multiple inventions examined in <u>Chapter II</u> if additional fees have been paid, so that there is no objection to be raised in the WO-IPEA.

In the case of a non-unitary application where no additional search fees were paid and the report on the first invention is positive, the IPER is also marked as negative (because the non-unity objection will prevent a direct grant upon entry into the European phase) and can be sent directly. Under Section V, a positive statement as to novelty and inventive step is given for the first invention only. Section IV is not filled out (see <u>GL/PCT-EPO C-V, 2</u>).

4. Rectification of the IPER

Rule 66.4bis

Since an IPER is a non-binding opinion and not a decision, the PCT provides for neither opposition nor appeal against it. Establishment of the IPER is normally the end of the international phase. Any further

observations or amendments the applicant wishes to make should therefore be addressed to the elected Offices and not to the IPEA.

Only when there is an error in the IPER or the IPER has been issued when in fact a second written opinion should have been issued (see <u>GL/PCT-EPO C-IV, 2.2</u>) will the file be transmitted to the examiner to decide whether or not to issue a corrected IPER.

GL/ISPE 19.34

In rare cases, the report may be incorrect, for example because it was based on wrong application documents or citations which are wrongly cited or are not comprised in the state of the art or on new documents cited for the first time in the IPER, or because amendments to the claims were overlooked.

In such cases, if there is at least one week before the actual deadline (normally 28 months from the priority date), a new Form 409 is completed with the correct information, and the corrected IPER is sent to the applicant and to WIPO.

GL/ISPE 19.35

If there is less than one week before that deadline, or if the deadline has expired, the applicant is called to ask whether he still wishes to receive a corrected IPER. If this is the case, a corrected IPER is issued. If the applicant declines to wait for a corrected IPER because of the deadline, Form 428 (minutes of telephone consultation) is completed, indicating the error in the IPER such that, in the regional phase, the applicant may cite the content of this form as evidence, and Form 428 is transmitted for information.

If, despite the applicant's request for rectification, the IPER does not contain any of the defects mentioned above, the formalities officer informs the applicant with a standard letter that the international preliminary examination phase has come to an end. Any further comments may only be addressed to the elected Offices on entry into the national phase.

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Chapter IX – Special requests

1. Withdrawal of demand under Chapter II

Applicants are entitled to a refund of 75% of the international preliminary examination fee if the demand is withdrawn before 30 months from the priority date and on condition that international preliminary examination has not started. If the examiner has actually started to examine the file, no refund will be made. The starting date of international preliminary examination can in most cases be derived from Form PCT/IPEA/409, which in Box I, point 6, indicates the date of the top-up search (Rule 70.2(f)). GL/PCT-EPO C-IV, 5.1, explains that the top-up search is conducted at the start of international preliminary examination and is usually not repeated before the IPER is issued.

Rule 58.3 Rule 90bis.4 Agreement EPO-WIPO Annex C-II OJ EPO 2010, 304

There is no provision for conditional withdrawal.

The signature of each applicant is required if the demand under Chapter II is withdrawn.

Rule 90bis.5

2. Request for examination of a different set of claims

The filing of different sets of claims for different elected States or of different (main and auxiliary) requests based on different sets of claims is not accepted since examining such claims is both time-consuming and against the intention of the PCT. Auxiliary requests are not provided for under the PCT because Rule 66.1(c) provides that, where Art. 19 amendments are made, the international preliminary examination is based on these amendments, unless they are superseded or reversed by a later amendment under Art. 34, and furthermore because Rule 70.16(a) provides for the annexing of the latest set of application documents to the IPER. The simultaneous examination of several co-pending requests is not compatible with the sequential consideration of single requests provided for in the above-mentioned Rules.

Rule 66.1(c) Rule 70.16(a)

If it is clear which request is the preferred (e.g. the main request), the WO-IPEA/IPER is established on that request; a remark is added in the WO-IPEA/IPER that the treatment of different requests (or main and auxiliary requests) is not provided for under the PCT.

If it is not clear which request is preferred (different requests with no preferred order), the applicant is asked, preferably by telephone, to furnish one set only or to state which set/request should be used for the examination.

If the applicant does not reply and/or insists on a plurality of sets, the WO-IPEA/IPER is drawn up on the first set, with a remark on the separate sheet under Section I.

3. Request for examination of certain claims only

Applicants sometimes file a request for examination of certain claims only without actually restricting the set of claims, e.g. in order to achieve a

positive IPER although the findings for some claims would be negative. An example would be where in reply to the WO-ISA, which contained a negative opinion on claims 1-5 and a positive one on claims 6 and 7, the applicant does not change the claims but asks that the IPER be established for claims 6 and 7 only.

Art. 34(3)(c) Art. 34(4)(a)(i) and (ii) Art. 35(2) A request for examination of certain claims only is not accepted since the IPER is established on the claims on file and can only be restricted by the examiner, e.g. on the grounds of lack of unity with not all fees paid, unsearched claims, clarity or added subject-matter. A restriction at the request of the applicant would be contrary to Art.35(2), which states that the IPER relates to "each claim". In such a case the applicant is informed that unless a restricted set of claims is filed the IPER will be established for all claims.

4. Complaint against the findings at the search stage

Art. 17(3)(a), Art. 17(2)(a)(i) and (ii) If the search was restricted and the applicant's reply contains a complaint against the findings at the search stage, the complaint will be dealt with by the Complaint Handling Unit at the EPO and a corrected ISR may have to be issued by the ISA.

PCT - Part E

Guidelines on General Procedural Matters

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Introduction

<u>Part E</u> contains guidelines for those procedural steps in respect of international applications which may occur at a number of stages in the procedure.

Chapter I – Observations by third parties

Third parties may, anonymously if so desired, file observations under the PCT which, unlike observations under the EPC, should exclusively refer to prior art relevant to the novelty and/or inventive step of the invention claimed in the international application.

AI 801-805 GL/ISPE 15.68, GL/ISPE 16.57 and GL/ISPE 17.69

The observations are to be submitted electronically to the IB between the date of international publication and 28 months from the priority date of the international application. They may be filed in any language of publication; the cited prior art may be in any language.

Rule 48.3

The applicant is notified by the International Bureau (IB) of any such observations and may file comments within 30 months from the priority date.

The IB will promptly communicate any third-party observation and any comment by the applicant to the ISA, the SISA and the IPEA, unless the (supplementary) international search report or the international preliminary examination report (IPER) has already been received by the IB.

Promptly after the expiration of 30 months from the priority date, the third-party observation(s) and the applicant's comment(s) will be sent to all designated Offices and elected Offices.

Any third-party observations/comments thereto will be made available for public inspection.

If the third-party observations and/or prior art are not in an official EPO language, the formalities officer at the EPO will invite the third party to submit a translation of the observations and/or the prior art in line with the European procedure (GL/EPO E-V, 3), but setting a shorter time limit within the boundaries of the required strict PCT deadlines. No invitation is issued if these deadlines cannot be respected or if the third-party observations were filed anonymously.

Art. 14(1) EPC

If the third-party observations and/or prior art are not in an official EPO language and a translation is not or cannot be filed, the examiner should nevertheless take them into account to the extent that this is feasible, in particular when they seem to be *prima facie* relevant (e.g. from the drawings of the prior-art documents). The examiner may add a remark in the WO-ISA that a translation will be required to allow a detailed assessment of the document(s).

Even when third-party observations have been filed, the deadlines indicated for issuing the different office actions under the PCT should be respected in order to ensure timely issuance of the ISR, SISR or IPER.

For third-party observations received during <u>Chapter I</u>, see <u>GL/PCT-EPO B-IV, 1.3</u>. For third-party observations received during <u>Chapter II</u>, see <u>GL/PCT-EPO C-VII, 3</u>.

Chapter II – Patent Prosecution Highway (PPH)

1. General

The Patent Prosecution Highway (PPH) enables an applicant whose claims have been determined to be patentable/allowable to have a corresponding application which has been filed with a PPH partner office processed in an accelerated manner while at the same time allowing the offices involved to exploit available work results.

Currently, the EPO's PPH partner offices are: JPO (Japan), KIPO (South Korea), SIPO (China), USPTO (USA), ILPO (Israel), CIPO (Canada), IMPI (Mexico) and IPOS (Singapore).

Under the PPH pilot programme a PPH request can be based on:

- the latest PCT work product (WO-ISA or IPRP/IPER) established by one of the PPH partner offices as ISA or IPEA (PPH based on PCT work products); or
- (ii) any national work product (office action indicating patentable/allowable claims) established during the processing of a national application or of a PCT application that has entered the national phase before one of the PPH partner offices (PPH based on national work products).

2. PPH based on a WO-ISA established by the EPO as ISA

Where the EPO is the ISA and the international application contains claims that are determined to be patentable/allowable by the EPO as ISA, the applicant may under the PPH pilot programme request accelerated examination at the EPO's PPH partner offices when the application has entered the national phase before these offices. The procedures and requirements for filing a request with the EPO's PPH partner offices are available from their respective websites.

OJ EPO 2014, A8, A6-A8 OJ EPO 2015, A70

Irrespective of the PPH pilot programme, any applicant may request accelerated examination under the PACE programme in the procedure before the EPO as designated Office at any time. See GL/EPO E-VII, 3.2.

OJ EPO 2015, A93

3. PPH based on an IPER established by the EPO as IPEA

Under the PPH pilot programme, a PPH request can also be based on an IPER established by the EPO as IPEA. The procedures and requirements for filing a request with the EPO's PPH partner offices are available from their respective websites.

OJ EPO 2014, A8, A6 OJ EPO 2015, A70

Irrespective of the PPH pilot programme, any applicant may request accelerated examination under the PACE programme in the procedure before the EPO as elected Office at any time. See <u>GL/EPO E-VII, 3.2</u>.

OJ EPO 2010, 352 OJ EPO 2015, A93

PCT - Part F

The International Application

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Chapter I – Introduction

Apart from the requirements of novelty, inventive step and industrial application, and the exclusion of subject-matter for which the ISA and/or IPEA is not required to carry out search and international preliminary examination, an international application must also satisfy a number of other requirements which are checked by the EPO as ISA and/or IPEA and reported on in the written opinion and/or IPER, as appropriate. These include substantive requirements such as sufficiency of disclosure (Art. 5), clarity of the claims (Art. 6) and unity of invention (Rule 13) as well as requirements of a more formal nature such as the numbering of the claims (Rule 6.1) and the form of the drawings (Rule 11.10 to 11.13). These requirements are dealt with in the present Part F.

Rule 43bis.1(a) Rule 66.2(a)

Part F also deals with the requirements relating to the right to priority.

Chapter II – Content of an international application (other than claims)

1. General

The contents of the international application are set out in <u>Article 3(2)</u>. The <u>GL/ISPE 4.01</u> application must contain:

- (i) a request;
- (ii) a description (see <u>GL/PCT-EPO F-II, 4</u>);
- (iii) one or more claims (see GL/PCT-EPO F-IV);
- (iv) one or more drawings (where required; see <u>GL/PCT-EPO F-II, 5</u>); and
- (v) an abstract (see GL/PCT-EPO F-II, 2).

This chapter discusses items (ii), (iv) and (v) insofar as they are the concern of the ISA and IPEA. Item (v) is dealt with first.

2. Abstract

2.1 Purpose of the abstract

An international application must contain an abstract. The abstract merely serves the purpose of technical information and cannot be taken into account for any other purpose, particularly not for the purpose of interpreting the scope of the protection sought.

Article 3(2), 3(3)

2.2 Definitive content

The abstract is initially supplied by the applicant subject to the exception provided for under <u>Rule 38.2</u>. The examiner conducting the main international search has the task of determining its definitive content, which will normally be published with the application. In doing this, he should consider the abstract in relation to the application as filed. If the search report is published later than the application, the abstract published with the application will be the one resulting from the procedure referred to in <u>ISPE Guidelines 15.40</u>.

Rules 8, 44.2

This procedure does not apply to supplementary international searches for which the EPO is SISA, because the main ISA has already provided the publication data (see <u>GL/PCT-EPO B-XII, 2</u>).

GL/ISPE 16.34

See also ISPE Guidelines 16.36.

2.3 Content of the abstract

See ISPE Guidelines 16.37.

See also GL/PCT-EPO B-X, 7.

2.4 Figure accompanying the abstract

Section F-II, 2.4, in the Guidelines for Examination in the EPO applies mutatis mutandis.

See also <u>ISPE Guidelines 16.37(c)</u> and <u>(e)</u> and <u>16.48-16.51</u> and <u>GL/PCT-EPO B-X, 7.</u>

2.5 Checklist

Section F-II, 2.5, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

2.6 Transmittal of the abstract to the applicant

Art. 18(2); Rule 44.2 The content of the abstract is transmitted to the applicant together with the search report (Form PCT/ISA/210, Box IV) (see <u>GL/PCT-EPO B-X, 7(i)</u>).

2.7 Comments on the abstract by the applicant

Rule 38.3

See ISPE Guidelines 16.40-16.43.

3. The title

Rules 4.3, 5.1(a)

The items making up the request do not normally concern the examiner, with the exception of the title. <u>Rule 5.1(a)</u> stipulates that the description "shall first state the title of the invention as appearing in the request".

The title must be short and precise. The examiner should review the title in the light of his reading of the description and claims and any amendments thereto, to make sure that the title, as well as being concise, gives a clear and adequate indication of the subject of the invention. Thus, if amendments are made which change the categories of claims, the examiner should check whether a corresponding amendment is needed in the title (see also GL/PCT-EPO B-X, 7). See also GL/PCT-EPO H-III, 7.

Rules 37, 44.2

For further provisions specifically related to the title, see <u>ISPE Guidelines</u> 16.44-16.47.

4. Description (formal requirements)

4.1 General remarks

Art. 5
Rule 5.1
GL/ISPE 4.02, 13.11
Section 204 PCT AI

Section F-II, 4.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

The usage of the subheadings outlined in Section 204 of the Administrative Instructions under the PCT is strongly recommended.

4.2 Technical field

Rule 5.1(a)(i)

See ISPE Guidelines 4.04.

4.3 Background art

Rule 5.1(a)(ii)

See ISPE Guidelines 4.05 and Appendix A4.05[1].

4.3.1 Format of background art citations

Section F-II, 4.3.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.3.1.1 Examples of quotation for non-patent literature

Section F-II, 4.3.1.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

4.3.1.2 Examples of quotation for patent literature

Section F-II, 4.3.1.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.4 Irrelevant matter

Section F-II, 4.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

See also GL/PCT-EPO F-II, 7.4.

4.5 Technical problem and its solution

See ISPE Guidelines 4.06-4.07.

Rules 5.1(a)(iii), 9.1(iii)

4.6 Reference in the description to drawings

See ISPE Guidelines 4.08.

4.7 Reference signs

See ISPE Guidelines 4.09.

4.8 Industrial applicability

The description should indicate explicitly the way in which the invention is capable of exploitation in industry, if this is not obvious from the description or from the nature of the invention (see also GL/PCT-EPO, G-III). The expression "capable of exploitation in industry" means the same as "susceptible of industrial application". In view of the broad meaning given to the latter expression in the Appendix to Chapter 14 of the ISPE Guidelines, A14.01[2].1(1) and A14.01[2].2, it is to be expected that, in most cases, the way in which the invention can be exploited in industry will be self-evident, so that no more explicit description on this point will be required; but there may be a few instances, e.g. in relation to methods of testing, where the manner of industrial exploitation is not apparent and must therefore be explicitly indicated.

Art. 33(1), (4) Rule 5.1(a)(vi) GL/ISPE A14.01[2]

Also, in relation to certain biotechnological inventions, i.e. sequences and partial sequences of genes, the industrial application is not self-evident and must be disclosed in the patent application.

4.9 Manner and order of presentation

See ISPE Guidelines 4.21.

Rule 5.1(b) Section 204 PCT AI

4.10 Terminology

See ISPE Guidelines 4.22.

Rule 10.2

4.11 Computer programs

See ISPE Guidelines 4.23.

4.12 Physical values, units

Rule 10.1(a), (b), (d), (e)

See <u>GL/ISPE 4.24</u>. See also <u>GL/EPO F-II, Annex 2</u>.

4.13 Registered trademarks

Section F-II, 4.14, in the Guidelines for Examination in the EPO applies mutatis mutandis.

5. Drawings

5.1 Form and content of the drawings

Rules 11.10-11.13

See ISPE Guidelines 4.28.

5.2 Photographs

PCT AG IP 5.159 GL/RO 146 The PCT Regulations are silent with regard to photographs. Nevertheless, they are allowed where what is to be shown (for instance, crystalline structures) cannot possibly be presented in a drawing. Where, exceptionally, photographs are submitted, they must be black and white, must be on sheets of A4 size, and must respect the minimum margins and admit of direct reproduction. Colour photographs are not accepted, nor are colour drawings.

Section F-II, 5.3, in the Guidelines for Examination in the EPO applies mutatis mutandis.

6. Nucleotide and amino acid sequence listings

Rule 5.2

See ISPE Guidelines 4.15 and Euro-PCT Guide, points 157-160.

For handling of non-compliant nucleotide and/or amino acid sequence listings at the search stage and during the <u>PCT Chapter II</u> procedure, see <u>GL/PCT-EPO B-VIII, 3.2</u> and <u>GL/PCT-EPO C-VIII, 2.1</u>, respectively.

6.1 Reference to sequences disclosed in a database

Section F-II, 6.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

7. Expressions, etc., not to be used

7.1 Categories

See ISPE Guidelines 4.29.

Rule 9.1

There are four categories of expressions which should not be contained in an international application, as specified in <u>Rule 9.1</u>. See <u>ISPE Guidelines 4.29</u>.

7.2 Expressions or drawings contrary to morality or public order

Rule 9.1(i) and (ii)

With regard to patentability issues with such matter, see <u>GL/PCT-EPO</u> <u>G-II, 4.1</u>.

7.3 Disparaging statements See ISPE Guidelines 4.30.	Rule 9.1(iii)
7.4 Irrelevant matter See ISPE Guidelines 4.31. See also GL/PCT-EPO F-II, 4.4.	<u>Rule 9.1(iv)</u>
7.5 Omission of matter from publication See ISPE Guidelines 4.32.	Art. 21(6)

PCT-EPO Guidelines

Part F - Chapter II-5

November 2016

Annex 1 Checklist for considering the abstract (see <u>GL/PCT-EPO F-II, 2.5</u>)

Annex 1 to Section F-II in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Annex 2 Units recognised in international practice (see <u>GL/PCT-EPO F-II, 4.12</u>)

Annex 2 to Section F-II in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Chapter III - Sufficiency of disclosure

1. Sufficiency of disclosure

A detailed description of at least one way of carrying out the invention must be given. Since the application is addressed to the person skilled in the art, it is neither necessary nor desirable that details of well-known ancillary features should be given, but the description must disclose any feature essential for carrying out the invention in sufficient detail to render it apparent to the skilled person how to put the invention into practice. A single example may suffice, but where the claims cover a broad field, the application should not usually be regarded as satisfying the requirements of Art. 5 unless the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims. However, regard must be had to the facts and evidence of the particular case. There are some instances where even a very broad field is sufficiently exemplified by a limited number of examples or even one example (see also GL/PCT-EPO F-IV, 6.3). In these latter cases the application must contain, in addition to the examples, sufficient information to allow the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill. In this context, the "whole area claimed" is to be understood as substantially any embodiment falling within the ambit of a claim, even though a limited amount of trial and error may be permissible, e.g. in an unexplored field or when there are many technical difficulties.

With regard to <u>Art. 5</u>, an objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts. See also <u>GL/PCT-EPO F-III, 4</u>.

For the requirements of <u>Art. 5</u> and of <u>Rule 5.1(iii)</u> and <u>(v)</u> to be fully satisfied, it is necessary that the invention is described not only in terms of its structure but also in terms of its function, unless the functions of the various parts are immediately apparent. Indeed in some technical fields (e.g. computers), a clear description of function may be much more appropriate than an over-detailed description of structure.

In cases where it is found that an application is sufficiently disclosed according to <u>Art. 5</u> only in respect of a part of the claimed subject-matter, it may be appropriate for the examiner to first invite the applicant to provide informal clarification before the search is carried out (see <u>GL/PCT-EPO B-VIII, 3.3-3.6</u>).

2. Sufficiency vs. additional subject-matter

See ISPE Guidelines 4.12.

3. Insufficient disclosure

See ISPE Guidelines 4.13.

GL/ISPE 5.45-5.51

Art. 5 Rule 5.1(iii) and (v)

Art. 5 Art. 34(2)(b)

Art. 5

If the claims for a perpetual motion machine are directed to its function, and not merely to its structure, an objection arises not only under <u>Art. 5</u> but also under <u>Art. 33(4)</u> in that the invention is not "industrially applicable" (see <u>GL/PCT-EPO G-III, 1</u>).

4. Burden of proof as regards the possibility of performing and repeating the invention

If there are serious doubts as regards the possibility of performing the invention and repeating it as described, the burden of proof as regards this possibility, or at least a demonstration that success is credible, rests with the applicant, who can discharge his burden of proof during the <u>PCT Chapter II</u> procedure or after entry into the European phase before the EPO. As regards the possibility of performing and repeating the invention, see also <u>GL/PCT-EPO F-III.</u> 3.

5. Cases of partially insufficient disclosure

5.1 Only variants of the invention are incapable of being performed Section F-III, 5.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*. See also GL/PCT-EPO G-VII, 5.2.

5.2 Absence of well-known details

GL/ISPE 5.50

Section F-III, 5.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*. See also GL/PCT-EPO F-III, 1 and F-IV, 4.5.

5.3 Difficulties in performing the invention

Section F-III, 5.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

6. Inventions relating to biological material

6.1 Biological material

Rule 13bis

See ISPE Guidelines 4.16-4.17.

6.2 Public availability of biological material

Section F-III, 6.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

6.3 Deposit of biological material

Rule 13bis.2
OJ EPO 2010, 498

See Euro-PCT Guide, points 150-156.

6.4 Priority claim

Section F-III, 6.4, in the Guidelines for Examination in the EPO applies mutatis mutandis.

7. Proper names, trademarks and trade names

See ISPE Guidelines 4.25.

For the assessment of the clarity of claims referring to a trademark (<u>Art. 6</u>), see <u>GL/PCT-EPO F-IV</u>, <u>4.8</u>.

8. Reference documents

See ISPE Guidelines 4.26.

Where the reference document relates to the background art, it may be in the application as originally filed or introduced at a later date (see GL/PCT-EPO F-II, 4.3, and GL/PCT-EPO H-II, 2.2.5).

Incorporation of essential matter or essential features at a later date is, however, subject to the restrictions set out in <u>GL/PCT-EPO H-II, 2.2.1</u>. It may be that the examiner has requested the applicant to furnish the document referred to, in order to be able to carry out a meaningful search (see <u>ISPE Guidelines 15.41</u>).

9. "Reach-through" claims

Section F-III, 9, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

10. Sufficiency of disclosure and Rule 20.5(e)

The application may contain sheets stamped "Not to be considered (R. 20.5(e) or 20.7)". This means that these sheets were not allowed by the receiving Office (for formal or substantive reasons) and the applicant has withdrawn those parts in order to avoid re-dating of the application. Such sheets thus do not form part of the application documents and should be ignored for search and examination.

In this case, the examiner must carefully evaluate whether the invention is still sufficiently disclosed without relying on the technical information contained in the withdrawn missing parts. Should the examiner reach the conclusion that the requirements of <u>Art. 5</u> are not satisfied, a corresponding objection is raised. See also <u>GL/PCT-EPO F-III, 3</u> to <u>5</u>.

11. Sufficiency of disclosure and clarity

An ambiguity in the claims may lead to an insufficiency objection. However, ambiguity also relates to the scope of the claims, i.e. <u>Art. 6</u> (see <u>GL/PCT-EPO F-IV, 4</u>). Normally, therefore, an ambiguity in a claim will lead to an objection under <u>Art. 5</u> only if the whole scope of the claim is affected, in the sense that it is impossible to carry out at all the invention defined therein. Otherwise an objection under <u>Art. 6</u> is appropriate.

In particular, where a claim contains an ill-defined ("unclear", "ambiguous") parameter (see also <u>GL/PCT-EPO F-IV. 4.11</u>) and where, as a consequence, the skilled person would not know whether he was working within or outside of the scope of the claim, this, by itself, is not a reason to deny sufficiency of disclosure as required by <u>Art. 5</u>. Nor is such a lack of clear definition necessarily a matter for objection under <u>Art. 6</u> only. What is decisive for establishing insufficiency within the meaning of <u>Art. 5</u> is whether the parameter, in the specific case, is so ill-defined that the skilled person is not able, on the basis of the disclosure as a whole and using his common general knowledge, to identify (without undue burden) the technical measures necessary to solve the problem underlying the application at issue.

GL/ISPE 4.12, 5.58

There is a delicate balance between $\underline{\text{Art. 5}}$ and $\underline{\text{Art. 6}}$ which has to be assessed on the merits of each individual case.

Chapter IV – Claims (<u>Art. 6</u> and formal requirements)

1. General

The international application must contain "one or more claims."

Art. 3(2), 6 GL/ISPE 5.01-5.02

The claims must:

- (i) "define the matter for which protection is sought;"
- (ii) "be clear and concise;" and
- (iii) "be fully supported by the description."

This chapter sets out the appropriate form and content of the claims, together with how they should be interpreted for the purposes of assessing the novelty and inventive step of the inventions which they define and searching for prior art which may be relevant to making that assessment.

For form-filling of the written opinion in case of formal defects or of clarity, conciseness or support issues, see GL/PCT-EPO B-XI, 3.2.4.

2. Form and content of claims

2.1 Technical features

Section F-IV, 2.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 6.3(a) GL/ISPE 5.04

It is not necessary that every feature should be expressed in terms of a structural limitation. Functional features are dealt with in <u>GL/PCT-EPO F-IV</u>, 6.5. For the specific case of a functional definition of a pathological condition, see <u>GL/PCT-EPO F-IV</u>, 4.22.

2.2 Two-part form

See ISPE Guidelines 5.05 and 5.22.

Rule 6.3(b)

2.3 Two-part form unsuitable

See ISPE Guidelines 5.06-5.07.

2.3.1 Two-part form "wherever appropriate"

See ISPE Guidelines 5.08.

2.4 Formulae and tables

See ISPE Guidelines 5.09.

Rule 11.10(a)-(c)

3. Kinds of claim

3.1 Categories

See ISPE Guidelines 5.12.

For activities practised upon living things, see <u>GL/PCT-EPO</u> <u>G-II, 4.2</u> and <u>5.4</u>, which relate to subject-matter that may be excluded from search or preliminary examination.

3.2 Number of independent claims

GL/ISPE 5.13-5.14

The PCT has no provision equivalent to <u>Rule 43(2) EPC</u>. However, plural independent claims in one category which comply with the requirement of unity of invention (see <u>GL/PCT-EPO F-V, 2</u>) may be objected to under <u>Art. 6</u> if they result in a lack of clarity and conciseness (see also <u>GL/PCT-EPO B-VIII, 4</u>).

When assessing whether to raise an objection of lack of clarity or conciseness for such claims, the examiner will take examples (i) to (iv) in GL/EPO F-IV, 3.2, into account.

3.3 Independent and dependent claims

Rules 6.4(a), 13.4 GL/ISPE 5.15-5.16 and A5.16[2] Section F-IV, 3.4, in the Guidelines for Examination in the EPO applies mutatis mutandis.

3.4 Arrangement of claims

GL/ISPE 5.17

Section F-IV, 3.5, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 6.4(a), (b), (c)

The EPO allows multiple dependent claims, provided that they do not detract from the clarity of the claims as a whole and that their arrangement does not create obscurity in the definition of the subject-matter to be protected. In case of unclarity, it may be appropriate for the examiner to first invite the applicant to provide informal clarification before the search is carried out (see GL/PCT-EPO B-VIII, 3.3-3.6).

See <u>GL/PCT-EPO F-IV, 3.7</u> for claims referring to a claim in a different category.

3.5 Subject-matter of a dependent claim

Section F-IV, 3.6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3.6 Alternatives in a claim

GL/ISPE 5.18

Section F-IV, 3.7, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

For the assessment of unity of invention of claims referring to alternatives, see <u>GL/PCT-EPO F-V, 4, 5</u> and <u>9</u>.

3.7 Independent claims containing a reference to another claim or to features from a claim of another category

GL/ISPE 5.19

Section F-IV, 3.8, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3.8 Claims directed to computer-implemented inventions

Section F-IV, 3.9, in the Guidelines for Examination in the EPO applies mutatis mutandis.

3.8.1 Cases where all method steps can be fully implemented by generic data processing means

Section F-IV, 3.9.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

3.8.2 Cases where method steps involve specific data processing means and/or require additional technical devices

Section F-IV, 3.9.2, in the Guidelines for Examination in the EPO applies mutatis mutandis.

4. Clarity and interpretation of claims

4.1 Clarity

See ISPE Guidelines 5.31.

Art. 6

Where it is found that the claims lack clarity, it may be appropriate for the examiner to first invite the applicant to provide informal clarification before the search is carried out (see <u>GL/PCT-EPO B-VIII, 3.3-3.6</u>).

4.2 Interpretation

See <u>ISPE Guidelines 5.20</u>. The EPO applies option <u>A5.20[2]</u> of the Appendix to Chapter 5 of the ISPE Guidelines.

4.3 Inconsistencies

See ISPE Guidelines 5.29 and 17.70.

4.4 General statements, "spirit" of invention

See ISPE Guidelines 5.30.

4.5 Essential features

4.5.1 Objections arising from missing essential features

Section F-IV, 4.5.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.5.2 Definition of essential features

Section F-IV, 4.5.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.5.3 Generalisation of essential features

Section F-IV, 4.5.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.5.4 Implicit features

See ISPE Guidelines 5.33.

4.5.5 Examples

Examples illustrating essential features can be found in the Annex to section F-IV in the Guidelines for Examination in the EPO.

4.6 Relative terms

See ISPE Guidelines 5.34.

4.7 Terms like "about" and "approximately"

GL/ISPE 5.38

Section F-IV, 4.7, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.8 Trademarks

See ISPE Guidelines 5.39.

See also <u>GL/PCT-EPO F-II, 4.13</u>, with regard to the need to acknowledge trademarks as such in the description. With regard to the effect of references to trademarks on sufficiency of disclosure (<u>Art. 5</u>), see <u>GL/PCT-EPO F-III, 7</u>.

4.9 Optional features

See ISPE Guidelines 5.40.

4.10 Result to be achieved

GL/ISPE 5.35

Section F-IV, 4.10, in the Guidelines for Examination in the EPO applies mutatis mutandis.

It should be noted that the requirements for allowing a definition of subject-matter in terms of a result to be achieved differ from those for allowing a definition of subject-matter in terms of functional features (see GL/PCT-EPO F-IV, 4.22 and 6.5).

Moreover, claims pertaining to a result to be achieved may likewise pose problems in the sense that essential features are missing (see GL/PCT-EPO F-IV, 4.5).

4.11 Parameters

GL/ISPE 5.36

Section F-IV, 4.11, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

For the assessment of novelty of claims containing parameters, see <u>GL/PCT-EPO G-VI, 6.</u>

Whether the method of and the means for measurement of the parameters need also be in the claim is dealt with in <u>GL/PCT-EPO F-IV, 4.18</u>. For further issues relating to clarity, lack of support and sufficiency of disclosure regarding parameters, see <u>GL/PCT-EPO F-III, 11</u>, and <u>F-IV, 6.4</u>.

4.12 Product-by-process claim

GL/ISPE 5.26

Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability, i.e. *inter alia* that they are new and inventive. A product is not

rendered novel merely by the fact that it is produced by means of a new process. A claim defining a product in terms of a process is to be construed as a claim to the product as such. The claim may for instance take the form "Product X obtainable by process Y". Irrespective of whether the term "obtainable", "obtained", "directly obtained" or an equivalent wording is used in the product-by-process claim, it is still directed to the product *per se* and confers absolute protection upon the product.

As regards novelty, when a product is defined by its method of manufacture, the question to be answered is whether the product under consideration is identical to known products. The burden of proof for an allegedly distinguishing "product-by-process" feature lies with the applicant, who has to provide evidence that the modification of the process parameters results in another product, for example by showing that distinct differences exist in the properties of the products. Nevertheless, the examiner needs to furnish reasoned argumentation to support the alleged lack of novelty of a product-by-process claim, especially if this objection is contested by the applicant.

The EPO applies option A5.26[1] of the Appendix to Chapter 5 of the ISPE Guidelines.

4.13 "Apparatus for ...", "Method for ...", etc.

Section F-IV, 4.13, in the Guidelines for Examination in the EPO applies mutatis mutandis.

GL/ISPE 5.21, 5.23

For claims directed to a known substance or composition for use in a surgical, therapeutic or diagnostic method, see <u>GL/PCT-EPO G-II</u>, <u>4.2</u>.

4.14 Definition by reference to use or another entity

Section F-IV, 4.14, in the Guidelines for Examination in the EPO applies *GL/ISPE 5.37* mutatis mutandis.

4.15 The expression "in"

Section F-IV, 4.15, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.16 Use claims

The EPO applies the first sentence concerning "use" claims of point <u>A5.21</u> <u>GL/ISPE A5.21</u> of the Appendix to Chapter 5 of the ISPE Guidelines.

Thus a claim in the form "the use of substance X as an insecticide" should not be interpreted as directed to the substance X recognisable (e.g. by further additives) as intended for use as an insecticide. Similarly, a claim for "the use of a transistor in an amplifying circuit" would be equivalent to a process claim for the process of amplifying using a circuit containing the transistor and should not be interpreted as being directed to "an amplifying circuit in which the transistor is used", nor to "the process of using the transistor in building such a circuit". However, a claim directed to the use of a process for a particular purpose is equivalent to a claim directed to that very same process.

Care should be taken when a claim relates to a two-step process which combines a use step with a product production step. This may be the case e.g. when a polypeptide and its use in a screening method have been defined as the only contribution to the art. An example of such a claim would then be:

"A method comprising:

- (a) contacting polypeptide X with a compound to be screened and
- (b) determining whether the compound affects the activity of said polypeptide;

and then formulating any active compound into a pharmaceutical composition."

Many variations of such a claim are conceivable, but in essence they combine (a) a screening step (i.e. using a specified test material to select a compound having a given property) with (b) further production steps (i.e. further transforming the selected compound for instance into the desired composition).

Two different types of process claim exist: (i) the use of an entity to achieve a technical effect and (ii) a process for the production of a product. The above claim and its analogues represent a combination of two different and irreconcilable types of process claim. Step (a) of the claim relates to a process of type (i), step (b) to a process of type (ii). Step (b) builds on the "effect" achieved by step (a), rather than step (a) feeding into step (b) a specific starting material and resulting in a specific product. This results in an unclear claim according to Art. 6.

4.17 References to the description or drawings

Rule 6.2(a)

See ISPE Guidelines 5.10.

4.18 Method of and means for measuring parameters referred to in

GL/ISPE 5.57

A further special case is where the invention is characterised by parameters (see <u>GL/PCT-EPO F-IV, 4.11</u>). Section <u>F-IV, 4.18</u>, in the <u>Guidelines for Examination in the EPO applies *mutatis mutandis*.</u>

4.19 Reference signs

Rule 6.2(b)

See <u>ISPE Guidelines 5.11</u>. If there is a large number of different embodiments, only the reference signs of the most important embodiments need be incorporated in the independent claim(s).

If text is added to reference signs in parentheses in the claims, lack of clarity can arise (Art. 6). Expressions such as "securing means (screw 13, nail 14)" or "valve assembly (valve seat 23, valve element 27, valve seat 28)" are not reference signs in the sense of Rule 6.2(b) but are special features. It is unclear whether the features added to the reference signs are limiting or not. Accordingly, such bracketed features are generally not

permissible. However, additional references to those figures, where particular reference signs are to be found, such as "(13 - Figure 3; 14 -Figure 4)", are unobjectionable.

A lack of clarity can also arise with bracketed expressions that do not include reference signs, e.g. "(concrete) moulded brick". In contrast, bracketed expressions with a generally accepted meaning are allowable, e.g.-"(meth)acrylate" which is known as an abbreviation for "acrylate and methacrylate". The use of brackets in chemical or mathematical formulae is also unobjectionable.

4.20 Negative limitations (e.g. disclaimers)

A claim's subject-matter is normally defined in terms of positive features indicating that certain technical elements are present. Exceptionally, however, the subject-matter may be restricted using a negative limitation expressly stating that particular features are absent. This may be done e.g. if the absence of a feature can be deduced from the application as filed.

GL/ISPE 5.41

Negative limitations such as disclaimers may be used only if adding positive features to the claim either would not define more clearly and concisely the subject-matter still protectable or would unduly limit the scope of the claim. It has to be clear what is excluded by means of the disclaimer. A claim containing one or more disclaimers must also fully comply with the clarity and conciseness requirements of Art. 6.

For the allowability of disclaimers excluding embodiments that were disclosed in the original application as being part of the invention, see GL/PCT-EPO H-III, 4.2. With respect to the allowability of a disclaimer not disclosed in the application as filed see GL/PCT-EPO H-III, 4.1.

4.21 "Comprising" vs. "consisting"

Section F-IV, 4.21, in the Guidelines for Examination in the EPO applies GL/ISPE 5.24(a), (b) mutatis mutandis.

4.22 Functional definition of a pathological condition

Section F-IV, 4.22, in the Guidelines for Examination in the EPO applies mutatis mutandis.

See also GL/PCT-EPO G-II, 4.2.

4.23 Broad claims

The PCT Regulations do not explicitly mention overly broad claims. GL/ISPE 5.42, 15.25 However, objections to such claims may arise for various reasons.

Where there are discrepancies between the claims and the description, the claims are not sufficiently supported by the description (Art. 6) and also, in most cases, the invention is not sufficiently disclosed (Art. 5, see GL/PCT-EPO F-IV, 6.1).

Sometimes an objection of lack of novelty arises, for example if the claim is formulated in such broad terms that it also covers known subject-matter from other technical fields. Broad claims may also cover embodiments for which a purported effect has not been achieved. On raising an objection of lack of inventive step in such cases, see <u>GL/PCT-EPO G-VII, 5.2</u>.

4.24 Order of claims

There is no legal requirement that the first claim should be the broadest. However, Art. 6 requires that the claims must be clear not only individually but also as a whole. Therefore, where there are a large number of claims, they should be arranged with the broadest claim first. If the broadest of a large number of claims is a long way down, so that it could easily be overlooked, the applicant should be required either to re-arrange the claims in a more logical way or to direct attention to the broadest claim in the introductory part or in the summary of the description.

Furthermore, if the broadest claim is not the first one, the later broader claim must also be an independent claim. Consequently, where these independent claims are of the same category, an objection may also arise under <u>Rule 6</u> if they result in a lack of clarity and conciseness (see <u>GL/PCT-EPO F-IV, 3.2</u>).

5. Conciseness, number of claims

Rule 6.1(a)

See ISPE Guidelines 5.42.

The EPO applies option <u>A5.42[2]</u> of the Appendix to Chapter 5 of the ISPE Guidelines.

Where it is found that the claims lack conciseness under <u>Art. 6</u>, it may be appropriate for the examiner to first invite the applicant to provide informal clarification before the search is carried out (see <u>GL/PCT-EPO B-VIII, 3.3-3.6</u>).

6. Support in description

6.1 General remarks

See ISPE Guidelines 5.43.

Regarding support for dependent claims by the description, see <u>GL/PCT-EPO F-IV</u>, <u>6.6</u>.

6.2 Extent of generalisation

See ISPE Guidelines 5.52.

An invention which opens up a whole new field is entitled to more generality in the claims than one which is concerned with advances in a known technology.

6.3 Objection of lack of support

See ISPE Guidelines 5.44.

Art. 6

Once the examiner has set out a reasoned case that, for example, a broad claim is not supported over the whole of its breadth, the onus of demonstrating that the claim is fully supported lies with the applicant (see GL/PCT-EPO F-III, 4).

The question of support is illustrated by examples (i) to (iii) in <u>GL/EPO F-IV</u>, 6.3. See also <u>ISPE Guidelines 5.53</u>.

Where it is found that the claims lack support in the description under <u>Art. 6</u>, it may be appropriate for the examiner to first invite the applicant to provide informal clarification before the search is carried out (see <u>GL/PCT-EPO B-VIII, 3.3-3.6</u>).

6.4 Lack of support vs. insufficient disclosure

It should be noted that, although an objection of lack of support is an objection under Art. 6, it can often, as in examples (i) to (iii) of GL/EPO F-IV, 6.3, also be considered as an objection of insufficient disclosure of the invention under Art. 5 (see GL/PCT-EPO F-III, 1 to 3), the objection being that the disclosure is insufficient to enable the skilled person to carry out the "invention" over the whole of the broad field claimed (although sufficient in respect of a narrow "invention"). Both requirements are designed to reflect the principle that the terms of a claim should be commensurate with, or be justified by, the invention's technical contribution to the art. Therefore, the extent to which an invention is sufficiently disclosed is also highly relevant to the issue of support. The reasons for failure to meet the requirements of Art. 5 may in effect be the same as those that lead to the infringement of Art. 6 as well, namely that the invention, over the whole range claimed, extends to technical subjectmatter not made available to the person skilled in the art by the application as filed.

For example, where a technical feature is described and highlighted in the description as being an essential feature of the invention, to comply with Art. 6 this must also be part of the independent claim(s) defining the invention (see <u>GL/PCT-EPO</u>, <u>F-IV</u>, 4.5.1). By the same token, if the (essential) technical feature in question is absent from the claims, and no information is given on how to perform the claimed invention successfully without the use of said feature, the description does not disclose the invention defined in the claim(s) in the manner prescribed by Art. 5.

An objection under both <u>Art. 5</u> and <u>Art. 6</u> may also be justified. An example would be a claim relating to a known class of chemical compounds defined by measurable parameters, when the description does not disclose a technical teaching allowing the skilled person to manufacture those compounds complying with the parametric definition, and this is not otherwise feasible by the application of common general knowledge or routine experimentation. Such a claim would be both technically not supported and not sufficiently disclosed, regardless of whether the parametric definition meets the clarity requirement of <u>Art. 6</u>.

Art. 5, 6

GL/ISPE 4.12, 5.58

6.5 Definition in terms of function

See ISPE Guidelines 5.56.

See also <u>GL/PCT-EPO F-IV, 2.1</u> and <u>4.10</u>.

6.6 Support for dependent claims

Section F-IV, 6.6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Annex

Examples concerning essential features

The Annex to Chapter IV of the Guidelines for Examination in the EPO contains examples of how to evaluate whether a claim contains all essential features of the invention. The examiner will apply the same criteria when assessing essential features under the PCT *mutatis mutandis*.

Chapter V - Unity of invention

1. General remarks

The international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Art. 17(3)(a) Rule 13.1

When determining unity of invention, a finding of lack of clarity of the claims is on its own not sufficient grounds for a finding of lack of unity.

Art. 6

Normally, too, the sequence of the claims should not have an impact on the determination of unity of invention. However, it will have an impact on which invention is to be considered the first invention mentioned in the claims (see GL/PCT-EPO F-V, 8.2).

Moreover, the fact that the claimed separate inventions belong to different groups of the classification is not in itself a reason for a finding of lack of unity.

An application may contain claims of different categories, or several independent claims of the same category. This is not in itself a reason for an objection of lack of unity of invention if the requirements of <u>Rules 13.1</u> to 13.3 are otherwise met.

With regard to substantive criteria, unity of invention is examined in search and substantive examination in both European and PCT procedures according to the same principles. This does not apply to the respective procedures themselves, where significant differences exist (see also GL/PCT-EPO B-VII).

Art. 150(2) EPC

2. Special technical features

See ISPE Guidelines 10.01 and 10.12-10.16.

Rule 13.2

See also <u>GL/PCT-EPO F-IV, 3.2</u> with regard to potential clarity and conciseness issues for plural independent claims in one category complying with the requirement of unity of invention.

3. Intermediate and final products

See ISPE Guidelines 10.18.

4. Alternatives

See ISPE Guidelines 10.09.

5. Markush grouping

See ISPE Guidelines 10.17.

There is no need for the significant structural element to be novel in absolute terms (i.e. novel *per se*). Rather, this expression means that in relation to the common property or activity there must be a common part of the chemical structure which distinguishes the claimed compounds from any known compounds having the same property or activity. However, if it

can be shown that at least one Markush alternative is not novel, unity of invention should be reconsidered. In particular, if the structure of at least one of the compounds covered by a Markush claim is known together with the property or technical effect under consideration, this is an indication of lack of unity of the remaining compounds (alternatives).

6. Individual features in a claim

See ISPE Guidelines 10.10.

See also GL/PCT-EPO G-VII, 7.

7. Lack of unity "a priori" or "a posteriori"

See ISPE Guidelines 10.03.

8. Examiner's approach

See ISPE Guidelines 10.04.

For the particular case of claims for a known substance for a number of distinct medical uses, see GL/PCT-EPO G-II, 4.2.

When there is lack of unity, the claimed subject-matter is divided among the separate inventions. In this context the word "invention" means an invention having technical character and concerned with a technical problem within the meaning of <u>Rule 5.1(iii)</u>, which does not necessarily need to meet other requirements for patentability, such as novelty and inventive step (see <u>GL/PCT-EPO G-VI</u> and <u>G-VII</u>).

8.1 Reasoning for a lack of unity objection

Rule 40.1(i)

Section F-V, 8.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

8.2 Determination of the invention first mentioned in the claims

Section F-V, 8.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

See also GL/PCT-EPO B-VII, 2.

9. Dependent claims

Rule 6.4 Rule 13.4 See ISPE Guidelines 10.06-10.08.

10. Lack of unity during search

Art. 17(3)(a) Rule 40 In many and probably most instances, lack of unity will have been noted at the search stage. In such cases, a search is conducted for the invention first mentioned in the claims and the applicant is invited to pay additional search fees with Form PCT/ISA/206. See GL/PCT-EPO B-VII, 2.

See also ISPE Guidelines 10.60.

11. Lack of unity during the PCT Chapter II procedure

Art. 34(3)(a)-(c) Rule 68 If an invitation to pay additional fees was issued during <u>Chapter I</u> and the applicant paid some or all of the required additional fees, and if, where

applicable, the objection as to lack of unity was at least partly upheld during a protest procedure, then under <u>Chapter II</u> the applicant will normally be invited (using Form 405) to pay additional preliminary examination fees if all the searched inventions are also to be examined under <u>Chapter II</u>. Inventions for which no search fees were paid cannot be pursued and will thus also not be objected to or commented on. See <u>GL/PCT-EPO C-V</u>.

See also ISPE Guidelines 10.71-10.73.

Chapter VI - Priority

1. The right to priority

For the establishment of the WO-ISA in relation to the priority claim, see GL/PCT-EPO B-XI, 4 and subsections.

1.1 Filing date as effective date

See ISPE Guidelines 6.01.

Art. 11, 14 Rule 20

1.2 Priority date as effective date

When an international application claims the right of priority of the date of filing of an earlier application, the priority date (i.e. the filing date of the earlier application) will be used to calculate certain time limits.

Art. 2(xi)

Furthermore, the priority date becomes the effective date for the purposes of international examination, i.e. the written opinion (of either the ISA or the IPEA) and the international preliminary examination report. The relevant date for the purposes of the international search is always the international filing date.

Rules 33.1, 43bis.1, 64.1 GL/ISPE 11.02-11.05

See ISPE Guidelines 6.02.

1.3 Validly claiming priority

See ISPE Guidelines 6.03.

Art. 8(1) Rules 2.4, 4.10 Rule 26bis.2 Art. 8(2)(a)

1.4 Subsequent application considered as first application

See ISPE Guidelines 6.04.

Examples of applications that cannot be recognised as a "first application" are:

- (i) US applications which are a "continuation" of a previous application ("con");
- (ii) US applications which are a "continuation in part" of a previous application ("cip"), in so far as the subject-matter in question was already disclosed in the original US application;
- (iii) national applications claiming priority from a previous national application or national utility model.

In the case of US con or cip applications, the first sentence of the description reads as follows: "This application is a continuation in part (continuation) of Serial Number filed". The following information is found on the title page under the heading "CONTINUING DATA******": "VERIFIED THIS APPLICATION IS A CIP (or CON) OF" A form headed "Declaration for Patent Application" must also be attached to the end of the application (in this case the priority document), listing earlier foreign or US applications under the heading "foreign priority benefits under

Title 35, United States Code, 119" or "benefit under Title 35, U.S.C., 120 of any United States application(s)".

1.5 Multiple priorities

Art. 8(1)

See ISPE Guidelines 6.05.

2. Determining priority dates

2.1 Examining the validity of a right to priority

See ISPE Guidelines 6.06.

2.2 The same invention

See ISPE Guidelines 6.07-6.09.

A disclaimer which is allowable under Art. 34(2)(b) (see GL/PCT-EPO H-III, 4.1 and 4.2) does not change the identity of the invention within the meaning of Art. 8. Therefore, such a disclaimer could be introduced when drafting and filing a successive international application, without affecting the right to priority from the first application not containing the disclaimer.

2.3 Priority claim not valid

See ISPE Guidelines 6.10.

3. Claiming priority

3.1 General remarks

Art. 11 Rule 4.10 See ISPE Guidelines 6.11.

3.2 Declaration of priority

Art. 8(1) Rule 4.10 See ISPE Guidelines 6.13-6.15.

Rules 17.1

3.3 Certified copy of the previous application (priority document) See Euro-PCT Guide, points 141-144.

3.5 Withdrawal of priority claims

and <u>66.7(a)</u>

3.4 Translation of the previous application

Rule 66.7(b)

See ISPE Guidelines 6.17.

Rule 90bis.3

The applicant may withdraw a priority claim, made in the international application under Article 8(1), at any time prior to the expiration of 30

months from the priority date.

3.6 Correction or addition of priority claim

Rule 26bis.1

See ISPE Guidelines 6.11, 6.16 and 8.10.

Rule 26bis.3 Th

3.7 Re-establishment of rights in respect of the priority period

The applicant may file a request for restoration of priority right up to two months after expiry of the priority year from the claimed priority.

In the international phase, restoration can be granted under both the "due care" and "unintentional" criteria. The EPO as receiving Office and as

designated Office in the regional phase will decide on the basis of the "due care" criterion (which is the same criterion as used for EP applications with respect to re-establishment of rights under <u>Art. 122 EPC</u>). If the EPO was not the receiving Office, the request may have been decided upon under the "unintentional" criterion.

If the priority right was restored by the receiving Office under the "due care" criterion, no new request need be filed with the EPO as designated/elected Office, since the EPO will, in principle, recognise the decision of the receiving Office. If, however, the EPO has reasonable doubt that the requirements for grant were not met, it will notify the applicant accordingly. In this communication the reasons for such doubt will be indicated and a time limit will be set within which the applicant may submit comments.

If the priority right was restored by the receiving Office under the "unintentional" criterion, a new request needs to be filed with the EPO as designated/elected Office, since the EPO is not bound by the decision of any receiving Office under the "unintentional" criterion.

For filling out the WO-ISA where the filing date exceeds the earliest priority date plus twelve and two months, see <u>GL/PCT-EPO B-XI, 4.1</u>

PCT - Part G

Substantive requirements of the application

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General disclaimer

Under <u>Art. 150(2) EPC</u>, an international application filed under the PCT may be the subject of proceedings before the EPO. In such proceedings, the provisions of the PCT and its Regulations are applied, supplemented by the provisions of the EPC. In case of conflict, the provisions of the PCT and its Regulations prevail.

The EPO, acting as ISA or IPEA, has established practice on how the examiner assesses novelty and inventive step. For most of the subject-matter this practice is identical to that used in proceedings for European patent applications. However, for some subject-matter the ISPE Guidelines deviate from the practice in European proceedings, and for other subject-matter they recognise that different offices adopt different approaches. As a result of Art. 153(2) EPC, the EPO as ISA/IPEA will, for the assessment of novelty and inventive step, generally apply the provisions of the PCT and, where these are not sufficient, will base its assessment on its established practice. In the latter case, these Guidelines then state that "the principles as laid down in the corresponding section in the Guidelines for Examination in the EPO apply mutatis mutandis."

It should be borne in mind that when an international application validly enters the regional phase before the EPO, it is considered as a European patent application. Consequently, the EPO will apply its criteria for examination as laid down in the Guidelines for Examination in the EPO for any subject-matter.

Chapter I - Patentability

The aim of the PCT is to allow the applicant to obtain an opinion on the patentability of the claimed subject-matter before entering the regional phase. The PCT procedure cannot serve the purpose of granting a patent as is the case for example under the EPC.

Art. 33(1) Rule 43bis.1(a)

November 2016 PCT-EPO Guidelines Part G – Chapter II-1

Chapter II – Inventions

1. General remarks

The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable.

Art. 33(1) Rule 43bis.1(a)

The PCT does not define what is meant by "invention", but <u>Rules 39</u> and <u>67</u> contain a list of subject-matter for which the ISA or IPEA is not required to carry out an international search or an international preliminary examination, respectively (see also <u>GL/PCT-EPO B-VIII, 2</u>). The Agreement between the EPO and WIPO in relation to the functioning of the EPO as an International Authority under the PCT indicates the subject-matter which the EPO is not required to search or examine, and according to its <u>Art. 4</u> and Annex B the discretion not to search or examine is exercised by the EPO as ISA and IPEA only to the extent that such subject-matter is not searched under the provisions of the EPC, specifically <u>Art. 52(2), (3)</u> and <u>53(b), (c) EPC</u>.

Art. 34(4)(a)(i) GL/ISPE 9.02–9.15 OJ 2010, 304

2. Examination practice

In carrying out the international preliminary examination, there are two general points the examiner must bear in mind. Firstly, any exclusion from patentability applies only to the extent to which the application relates to the excluded subject-matter as such. Secondly, the subject-matter of the claim should be considered as a whole, in order to decide whether the claimed subject-matter has a technical character.

3. List of exclusions

See ISPE Guidelines 9.02–9.15.

3.1 Discoveries

<u>Rules 39.1</u> and <u>67.1</u> do not explicitly exclude an international search or international preliminary examination on discoveries from being carried out by the ISA or IPEA, respectively. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 52(2)(a)</u> and <u>(3) EPC</u>. Section <u>G-II, 3.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.</u>

Rules 39.1, 67.1 PCT AG I 7.013

3.2 Scientific theories

See <u>ISPE Guidelines 9.05</u>. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 52(2)(a)</u> and <u>(3) EPC</u>. Section <u>G-II, 3.2</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

Rules 39.1(i),67.1(i)

3.3 Mathematical theories

See <u>ISPE Guidelines 9.05</u>. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 52(2)(a)</u> and <u>(3) EPC</u>. Section <u>G-II, 3.3</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

Rules 39.1(i), 67.1(i)

3.4 Aesthetic creations

Rules 39.1 and 67.1 do not explicitly exclude an international search or international preliminary examination on aesthetic creations from being carried out by the ISA or IPEA, respectively. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(b) and (3) EPC. Section G-II, 3.4, in the Guidelines for Examination in the EPO applies mutatis mutandis.

3.5 Schemes, rules and methods of doing business, performing purely mental acts or playing games

Rules 39.1(iii), 67.1(iii)

See ISPE Guidelines 9.07, A9.07 and A9.07[2]. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(c) and (3) EPC. Section G-II, 3.5, in the Guidelines for Examination in the EPO applies mutatis mutandis.

3.6 Programs for computers

Rules 39.1(vi), 67.1(vi)

See <u>ISPE Guidelines 9.15</u>, <u>A9.15</u> and <u>A9.15[2]</u>. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 52(2)(c)</u> and <u>(3) EPC</u>. Section <u>G-II, 3.6</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis* (cf. <u>GL/PCT-EPO B-VIII, 2.2</u>).

3.7 Presentations of information

Rules 39.1(v), 67.1(v)

See <u>ISPE Guidelines 9.11-9.14</u>. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 52(2)(d)</u> and <u>(3) EPC</u>. Section <u>G-II, 3.7</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

4. Exclusions from and limitation of international preliminary examination

4.1 Matter contrary to "ordre public" or morality

Art. 21(6) Rule 9 PCT AG I 5.175 Unlike the EPC, the PCT does not explicitly define subject-matter which is considered to contravene "ordre public" or morality. According to Rule 9, the application must not contain any expressions contrary thereto, and under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 53(a) EPC. Generally, no search or preliminary examination is carried out by the EPO as ISA/IPEA. Section G-II, 4.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

4.2 Surgery, therapy and diagnostic methods

Rules 39.1(iv), 67.1(iv) See <u>ISPE Guidelines 9.08-9.10</u>. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 53(c) EPC</u>. Generally, no search or preliminary examination is carried out by the EPO as ISA/IPEA. Section <u>G-II, 4.2</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

November 2016 PCT-EPO Guidelines Part G – Chapter II-3

5. Exclusions and exceptions for biotechnological inventions

5.1 General remarks and definitions

"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

Rules 39.1(ii), 67.1(ii)

5.2 Biotechnological inventions

See <u>ISPE Guidelines 9.06</u>. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 53(b) EPC</u>. Generally, no search or preliminary examination is carried out by the EPO as ISA/IPEA. Section <u>G-II, 5.2</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

5.3 Exceptions

The PCT, unlike the EPC, does not explicitly exclude carrying out an international search or an international preliminary examination on specific subject-matter related to biotechnological inventions. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under <u>Art. 53 EPC</u>. Generally, no search or preliminary examination is carried out by the EPO as ISA/IPEA. Section <u>G-II, 5.3</u>, in the <u>Guidelines for Examination in the EPO</u> applies *mutatis mutandis*.

5.4 Plant and animal varieties, essentially biological processes for the production of plants or animals

See ISPE Guidelines 9.06. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 53(b) EPC. Generally, no search or preliminary examination is carried out by the EPO as ISA/IPEA. Section G-II, 5.4 and subsections, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rules 39.1(ii), 67.1(ii)

5.5 Microbiological processes

See <u>ISPE Guidelines 9.06</u>. However, once the application enters the regional phase before the EPO, section <u>G-II, 5.5</u> and subsections, in the Guidelines for Examination in the EPO applies.

Rules 39.1(ii), 67.1(ii)

November 2016 PCT-EPO Guidelines Part G – Chapter III-1

Chapter III - Industrial application

1. General remarks

See ISPE Guidelines 14.01-14.03.

Art. 33(4)

2. Methodology

See ISPE Guidelines 14.04-14.06.

3. Industrial applicability

See ISPE Guidelines A14.01[2].

Chapter IV - Prior art

1. General remarks and definition

An invention is to be "considered novel if it is not anticipated by the prior art". The "prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and 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 (i.e., that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date". The scope of this definition should be noted. There are no restrictions whatsoever as to the geographical location where or the language in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information.

Art. 33(2), (3) Rules 33.1(a), (b), 64.1

See also ISPE Guidelines 11.01 and 11.12.

The principles to be applied in determining whether other kinds of prior art, e.g. relating to use (which could be introduced e.g. by a third party, see <u>GL/PCT-EPO E-I</u>, <u>ISPE Guidelines 16.57</u> and PCT/AI section 801), have been made available to the public are governed by <u>Rules 33.1(b)</u> and <u>64.2</u>.

For the examination of the novelty of claimed subject-matter, see <u>GL/PCT-EPO G-VI</u>.

Art. 33(2)

A written description, i.e. a document, should be regarded as made available to the public if, at the relevant date, it was possible for members of the public to gain knowledge of the content of the document and there was no bar of confidentiality restricting the use or dissemination of such knowledge. For instance, German utility models ("Gebrauchsmuster") are already publicly available as of their date of entry in the Register of utility models ("Eintragungstag"), which precedes the date of announcement in the Patent Bulletin ("Bekanntmachung im Patentblatt").

2. Enabling disclosures

The principles as laid down in section <u>G-IV, 2</u>, in the <u>Guidelines for Examination in the EPO</u> apply *mutatis mutandis*.

3. Date of filing or priority date as effective date

It should be noted that for the purpose of international preliminary examination all prior art is taken into account which was publicly available before the international filing date or, where a priority has been validly claimed, before the date of priority. It should be remembered that different claims, or different alternatives claimed in one claim, may have different effective dates, i.e. the date of filing or (one of) the claimed priority date(s). The question of novelty must be considered against each claim (or part of a claim where a claim specifies a number of alternatives), and prior art in relation to one claim or one part of a claim may include matter, e.g. an intermediate document (see <u>GL/PCT-EPO B-X, 9.2.4</u>), which cannot be

Rule 64.1(a), (b) GL/ISPE 11.24-11.26 cited against another claim or another alternative in the same claim because it has an earlier effective date.

Rule 20.5

If the applicant subsequently furnishes missing parts of the description, parts of the claims or all or parts of the drawings under <u>Rule 20.5</u>, the accorded date of the application is the date on which all the requirements of <u>Art. 11(1)</u> are fulfilled, unless they are completely contained in the priority document and the requirements given in <u>Rule 20.6</u> are satisfied, in which case the original filing date is maintained. The date of the application as a whole is thus either the date of filing of the missing parts or the original filing date (see <u>GL/PCT-EPO C-III, 2</u>, and <u>GL/PCT-EPO H-II, 2.2.2</u>).

4. Documents in a non-official language of the (S)ISA or IPEA If the applicant

- (i) disputes the relevance of a document in a non-official language cited in the search report (for procedure at the search stage, see GL/PCT-EPO B-X, 9.1.2 and 9.1.3), and
- (ii) gives specific reasons,

the examiner should consider whether, in the light of these reasons and of the other prior art available to him, he is justified in pursuing the matter. If so, he should obtain a translation of the document (or merely the relevant part of it if that can be easily identified). If he remains of the view that the document is relevant, he should send a copy of the translation to the applicant with the next communication in the <u>PCT Chapter II</u> phase.

4.1 Machine translations

In order to overcome the language barrier constituted by a document in an unfamiliar non-official language, it might be appropriate for the examiner to rely on a machine translation of said document, which should be sent to the applicant. If only part of the translated document is relevant, the particular passage relied upon should be identified. A translation has to serve the purpose of rendering the meaning of the text in a familiar language. Therefore mere grammatical or syntactical errors which have no impact on the possibility of understanding the content do not hinder its qualification as a translation.

A general statement that machine translations as such cannot be trusted is not sufficient to contest the value of the translation. If the applicant objects to the use of a specific machine translation, he bears the burden of adducing evidence (in the form of, for instance, an improved translation of the whole or salient parts of the document) showing the extent to which the quality of the machine translation is defective and should therefore not be relied upon.

When the applicant provides substantiated reasoning for questioning the objections raised based on the translated text, the examiner will have to take these reasons into account, similarly to when the publication date is questioned.

November 2016 PCT-EPO Guidelines Part G – Chapter IV-3

5. Conflict with other applications

5.1 Prior art pursuant to Rule 64.3

Under the PCT, the prior art does not comprise the content of other applications filed or validly claiming a priority date earlier than – but published on or after – the date of filing or valid date of priority of the application being examined. However, attention must be drawn to such applications in the preliminary examination report, as they may become relevant under <u>Article 54(3) EPC</u> (see also <u>GL/PCT-EPO B-XI, 4.3</u>). By the "content" of an application is meant the whole disclosure, i.e. the description, drawings and claims, including:

GL/ISPE 11.07-11.09 Rule 64.3

- any matter explicitly disclaimed (with the exception of disclaimers for unworkable embodiments);
- (ii) any matter for which an allowable reference (see <u>GL/EPO F-III, 8</u>, penultimate paragraph) to other documents is made; and
- (iii) prior art insofar as explicitly described.

However, the "content" does not include any priority document (the purpose of such document being merely to determine to what extent the priority date is valid for the disclosure of the international application).

5.2 Co-pending applications

The PCT does not deal explicitly with the case of co-pending international applications of the same applicant of the same effective date, see <u>ISPE</u> <u>Guidelines 11.10</u>.

6. Prior art made available to the public anywhere in the world by non-written disclosure

A non-written disclosure is not considered part of the prior art for the purposes of <u>Art. 33(2)</u> and <u>(3)</u> if the date of that non-written disclosure is indicated in a written disclosure which has been made available to the public on or after the relevant date of the application (i.e. on or after the international filing date or, if a priority has been validly claimed, the earliest priority date).

Rule 64.2

6.1 Types of non-written disclosure, in particular use, and instances of prior art made available in any other way

Making available to the public may occur by means of an oral disclosure, use, exhibition or other non-written means. Use may be constituted by producing, offering, marketing or otherwise exploiting a product, or by offering or marketing a process or its application or by applying the process. Marketing may be effected, for example, by sale or exchange.

Rules 33.1(b), 64.2

Prior art may also be made available to the public in other ways, as for example by demonstrating an object or process in specialist training courses or on television.

Availability to the public in any other way also includes all possibilities which technological progress may subsequently offer of making available the aspect of the prior art concerned.

It should be borne in mind that for the purposes of the international preliminary examination a non-written disclosure is to be considered part of the prior art for the purposes of <u>Art. 33(2)</u> and <u>(3)</u> only if its content is confirmed by a written disclosure that was made available to the public earlier than the relevant date as defined by Rule 64.1(b).

6.2 Matters to be determined by the IPEA as regards use

Rule 64.2

When the IPEA has gained knowledge of an object or process that has been used in such a way that it is comprised in the prior art (e.g. by a third party, see <u>GL/PCT-EPO E-I</u>, <u>ISPE Guidelines 16.57</u> and PCT/AI section 801), the following details have to be determined:

- (i) whether there is a written disclosure that was made available to the public earlier than the relevant date as defined by <u>Rule 64.1(b)</u> which confirms the use of the object or the process;
- (ii) the date on which an alleged use occurred, i.e. whether there was any instance of use before the relevant date (prior use);
- (iii) what has been used, in order to determine the degree of similarity between the object used and the subject-matter of the application; and
- (iv) all the circumstances relating to the use, in order to determine whether and to what extent it was made available to the public, as for example the place of use and the form of use. These factors are important in that, for example, the details of a demonstration of a manufacturing process in a factory or of the delivery and sale of a product may well provide information as regards the possibility of the subject-matter having become available to the public.

6.2.1 General principles

Subject-matter should be regarded as made available to the public by use or in any other way if, at the relevant date, it was possible for members of the public to gain knowledge of the subject-matter and there was no bar of confidentiality restricting the use or dissemination of such knowledge. This may, for example, arise if an object is unconditionally sold to a member of the public, since the buyer thereby acquires unlimited possession of any knowledge which may be obtained from the object. Even where in such cases the specific features of the object may not be ascertained from an external examination, but only by further analysis, those features are nevertheless to be considered as having been made available to the public. This is irrespective of whether or not particular reasons can be identified for analysing the composition or internal structure of the object. These specific features only relate to the intrinsic features. Extrinsic characteristics, which are only revealed when the product is exposed to interaction with specifically chosen outside conditions, e.g. reactants or

the like, in order to provide a particular effect or result or to discover potential results or capabilities, therefore point beyond the product *per se* as they are dependent on deliberate choices being made. Typical examples are the first or further application as a pharmaceutical product of a known substance or composition and the use of a known compound for a particular purpose, based on a new technical effect. Thus, such characteristics cannot be considered as already having been made available to the public.

If, on the other hand, an object could be seen in a given place (a factory, for example) to which members of the public not bound to secrecy, including persons with sufficient technical knowledge to ascertain the specific features of the object, had access, all knowledge which an expert was able to gain from a purely external examination is to be regarded as having been made available to the public. In such cases, however, all concealed features which could be ascertained only by dismantling or destroying the object will not be deemed to have been made available to the public.

6.2.2 Agreement on secrecy

The basic principle to be adopted is that subject-matter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken, or if the circumstances of the case are such that such secrecy derives from a relationship of good faith or trust. Good faith and trust are factors which may occur in contractual or commercial relationships.

6.2.3 Use on non-public property

As a general rule, use on non-public property, for example in factories and barracks, is not considered as use made available to the public, because company employees and soldiers are usually bound to secrecy, save in cases where the objects or processes used are exhibited, explained or shown to the public in such places, or where specialists not bound to secrecy are able to recognise their essential features from the outside. Clearly the above-mentioned "non-public property" does not refer to the premises of a third party to whom the object in question was unconditionally sold or the place where the public could see the object in question or ascertain features of it.

6.2.4 Example of the accessibility of objects used

A press for producing light building (hard fibre) boards was installed in a factory shed. Although the door bore the notice "Unauthorised persons not admitted", customers (in particular dealers in building materials and clients who were interested in purchasing light building boards) were given the opportunity of seeing the press although no form of demonstration or explanation was given. An obligation to secrecy was not imposed as, according to witnesses, the company did not consider such visitors as a possible source of competition. These visitors were not genuine specialists, i.e. they did not manufacture such boards or presses, but were not entirely laymen either. In view of the simple construction of the press, the essential features of the invention concerned were bound to be evident to anyone observing it. There was therefore a possibility that these customers, and in

particular the dealers in building materials, would recognise these essential features of the press and, as they were not bound to secrecy, they would be free to communicate this information to others.

6.2.5 Example of the inaccessibility of a process

The subject of the patent concerns a process for the manufacture of a product. As proof that this process had been made available to the public by use, a similar already known product was asserted to have been produced by the process claimed. However, it could not be clearly ascertained, even after an exhaustive examination, by which process it had been produced.

6.3 Prior art made available by means of oral description

Rules 64.2, 70.9 GL/ISPE 11.22 If the prior art was made available to the public by an oral description before the relevant date (i.e. the date of filing of the application or, if applicable, the date of the earliest validly claimed priority, <u>Rule 64.1</u>) but a document which reproduces the oral description was only published on or after that relevant date, the written opinion and the IPER draw attention to this non-written disclosure in the manner provided for in <u>Rule 70.9</u>.

6.4 Internet disclosures

GL/ISPE 11.13-11.20

As a matter of principle, disclosures on the internet form part of the prior art. Information disclosed on the internet or in online databases is considered to be publicly available as of the date the information was publicly posted. Internet websites often contain highly relevant technical information. Certain information may even be available only on the internet from such websites. This includes, for example, online manuals and tutorials for software products (such as video games) or other products with a short life cycle.

As regards establishing the publication date and the standard and burden of proof, in particular with technical journals or "print equivalent" publications, the principles as laid down in the Guidelines for Examination in the EPO (GL/EPO G-IV, 7.5.1 and subsections) apply *mutatis mutandis*.

6.5 Standards and standard preparatory documents

The principles as laid down in the Guidelines for Examination in the EPO (G-IV, 7.6) apply *mutatis mutandis*.

7. Cross-references between prior art documents

If a document (the "primary" document) refers explicitly to another document (the "secondary" document) as providing more detailed information on certain features, the teaching of the latter is to be regarded as incorporated into the primary document if the document was available to the public on the publication date of the primary document. The relevant date for novelty purposes, however, is always the date of the primary document.

8. Errors in prior art documents

Errors may exist in prior art documents. If, using common general knowledge, the skilled person can

- (i) see at once that the disclosure of a relevant prior art document contains errors, and
- (ii) identify what the only possible correction should be,

then the errors in the disclosure do not affect its relevance as prior art. The document can thus be considered to contain the correction when assessing its relevance to patentability.

Chapter V – Non-prejudicial disclosures

1. General

The PCT acknowledges that in certain cases the invention may have been disclosed before the relevant date for the purposes of the PCT in such a way that it is not considered to form part of the prior art in accordance with the national law of one or more designated Offices (Rule 51bis.1(a)(v)).

GL/ISPE 11.22 PCT/AI Section 215 Rule 4.17(v)

Therefore, it should be borne in mind that, upon validly entering the regional phase before the EPO, the standards for non-prejudicial disclosures as laid down in <u>Article 55(1) EPC</u> will be applied.

Consequently, the principles as laid down in Chapter <u>G-V of the Guidelines</u> <u>for Examination in the EPO</u> apply *mutatis mutandis*.

Chapter VI - Novelty

1. Prior art pursuant to Art. 33(2)

Under the PCT, an invention is considered to be novel if it is not anticipated by the prior art. Everything which is made available to the public anywhere in the world by means of a written disclosure is considered prior art provided that such making available occurred prior to the relevant date. In cases where the making available to the public occurred by non-written means, it constitutes prior art only if a written disclosure that occurred before the relevant date confirms the non-written disclosure. The relevant date is the international filing date or, where at least one priority has been validly claimed, the date of the earliest priority. It should be noted that in considering novelty (as distinct from inventive step), it is not permissible to combine separate items of prior art together. It is also not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested, see also ISPE Guidelines 12.06.

Art. 33(2) Rule 43bis.1(a)(i), 64.1, 64.2 GL/ISPE 12.01, 12.02

For the specific case of selection inventions see ISPE Guidelines 12.10.

Furthermore, any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) and prior art acknowledged in a document, insofar as explicitly described therein, are to be regarded as incorporated in the document.

It is further permissible to use a dictionary or similar document of reference in order to interpret a special term used in a document.

GL/ISPE 12.06

2. Implicit features or well-known equivalents

A document takes away the novelty of any claimed subject-matter derivable directly and unambiguously from that document including any features implicit to a person skilled in the art in what is expressly mentioned in the document, e.g. a disclosure of the use of rubber in circumstances where clearly its elastic properties are used even if this is not explicitly stated takes away the novelty of the use of an elastic material. The limitation to subject-matter "derivable directly and unambiguously" from the document is important. Thus, when considering novelty, it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the documents; this is a matter of inventive step.

GL/ISPE 12.04

3. Relevant date of a prior document

In determining novelty, a prior document should be read as it would have been read by a person skilled in the art on the relevant date of the document. For the purpose of assessing novelty the "relevant" date for written disclosures is the date as defined by <u>Rule 64.1(b)</u>, i.e. either the international filing date of the application under consideration or, if a priority has been validly claimed, the application date of that earlier application (if the filing date of the application is within the two-month period after the expiry of the priority period of the earlier application, the relevant date is

Rule 64.1, 64.2

also the application date of that earlier application); for non-written disclosures see Rule 64.2.

4. Enabling disclosure of a prior document

GL/ISPE 12.02

Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the prior art pursuant to <u>Rule 64</u>, if the information given therein to the skilled person is sufficient to enable him, at the relevant date of the document, to practise the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field to be expected of him.

Similarly, it should be noted that a chemical compound, the name or formula of which is mentioned in a prior-art document, is not thereby considered as known, unless the information in the document, together, where appropriate, with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.

5. Generic disclosure and specific examples

GL/ISPE 12.08, 12.09

In considering novelty, it should be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure, e.g. a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper, and one of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets.

6. Implicit disclosure and parameters

GL/ISPE 12.04

In the case of a prior document, the lack of novelty may be apparent from what is explicitly stated in the document itself. Alternatively, it may be implicit in the sense that, in carrying out the teaching of the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. An objection of lack of novelty of this kind should be raised by the examiner only where there can be no reasonable doubt as to the practical effect of the prior teaching. Situations of this kind may also occur when the claims define the invention, or a feature thereof, by parameters. It may happen that in the relevant prior art a different parameter, or no parameter at all, is mentioned. If the known and the claimed products are identical in all other respects (which is to be expected if, for example, the starting products and the manufacturing processes are identical), then in the first place an objection of lack of novelty arises. The burden of proof for an alleged distinguishing feature lies with the applicant. No benefit of doubt can be accorded if the applicant does not provide evidence in support of the allegations. If, on the other hand, the applicant is able to show, e.g. by appropriate comparison tests, that differences do exist with respect to the parameters, it is questionable whether the application discloses all the features essential to manufacture products having the parameters specified in the claims (Art. 5).

7. Examination of novelty

In determining novelty of the subject-matter of claims, the examiner should remember that, particularly for claims directed to a physical entity, non-distinctive characteristics of a particular intended use should be disregarded. For example, a claim to a substance X for use as a catalyst would not be considered to be novel over the same substance known as a dye, unless the use referred to implies a particular form of the substance (e.g. the presence of certain additives) which distinguishes it from the known form of the substance. That is to say, characteristics not explicitly stated, but implied by the particular use, should be taken into account.

GL/ISPE 12.05

A known compound is not rendered novel merely because it is available with a different degree of purity if the purity can be achieved by conventional means.

7.1 Second or further medical use of known pharmaceutical products

How the novelty of second or further medical use claims is assessed depends on the IPEA. The examiner at the EPO as IPEA examines the novelty of the subject-matter in view of the entry into the regional phase before the EPO and therefore will apply the principles as laid down in <u>GL/EPO G-VI, 7.1</u> and subsections. See <u>GL/PCT-EPO B-VIII, 2.1</u>, for the treatment of medical use claims by the EPO as ISA.

7.2 Second non-medical use

A claim to the use of a known compound for a particular purpose (second non-medical use) which is based on a technical effect will be interpreted by the EPO examiner as including that technical effect as a functional technical feature. The novelty of the use of the known compound for the known production of a known product cannot be deduced from a new property of the produced product. In such a case, the use of a compound for the production of a product will be interpreted as a process for production of the product with the compound. Therefore, it can be regarded as novel only if the process of production as such is novel.

8. Selection inventions

Selection inventions deal with the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned, within a larger known set or range. The examiner of the EPO as IPEA will assess the novelty of the subject-matter according to the principles laid down in <u>GL/EPO G-VI, 8</u> and subsection.

GL/ISPE 12.10

9. Novelty of "reach-through" claims

"Reach-through" claims are defined as claims attempting to obtain protection for a chemical product (and also uses thereof, compositions thereof, etc.) by defining that product functionally in terms of its action (e.g. agonist, antagonist) on a biological target such as an enzyme or receptor. In many such cases, the applicant functionally defines chemical compounds in this way by reference to a newly identified biological target. However, compounds which bind to and exercise this action on that biological target are not necessarily novel compounds simply because the

biological target which they act on is new. Indeed in many cases, the applicant himself provides test results in the application whereby known compounds are shown to exert this action on the new biological target, thus demonstrating that compounds falling within the functional definition of the "reach-through" claim are known in the prior art and so establishing that a reach-through claim relating to compounds defined in this way lacks novelty.

Chapter VII - Inventive step

1. General

An invention is considered to involve an inventive step if, having regard to the prior the art, it is not obvious to a person skilled in the art. Novelty and inventive step are different criteria. The question of whether there is inventive step only arises if the invention is novel.

Art. 33(3) GL/ISPE 13.01

2. Prior art; date of filing, date of priority

The "prior art" for the purposes of considering inventive step is as defined in <u>Art. 33(3)</u>.

GL/ISPE 13.02

In determining what is to be considered prior art, the principles laid down in <u>GL/PCT-EPO G-IV</u> apply.

3. Person skilled in the art

The "person skilled in the art" should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "prior art", in particular the documents cited in the search report, and to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The skilled person is involved in constant development in his technical field.

GL/ISPE 13.11

3.1 Common general knowledge of the skilled person

Section G-VII, 3.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4. Obviousness

Thus the question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim, having regard to the art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is not allowable for lack of inventive step. The term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. In considering inventive step, as distinct from novelty, it is fair to construe any published document in the light of knowledge up to and including the day before the relevant date according to Rule 65.2 for the claimed invention and to have regard to all the knowledge generally available to the person skilled in the art up to and including that day.

Rule 65.1 GL/ISPE 13.03, 13.09, 13.10

5. Problem-and-solution approach

GL/ISPE 13.08, A13.08.1-A13.08.9 In order render the assessment of inventive step more objective, the EPO, acting as IPEA under <u>PCT Chapter II</u>, uses the so-called "problem-and-solution approach", which should be applied consistently.

In the problem-and-solution approach, there are three main stages:

- (i) determining the "closest prior art",
- (ii) establishing the "objective technical problem" to be solved, and
- (iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

5.1 Determination of the closest prior art

GL/ISPE 13.10, A13.08.2 Generally, the principles laid down in section G-VII, 5.1, in the Guidelines for Examination in the EPO apply mutatis mutandis. The closest prior art is that which in one single reference discloses the combination of features which constitutes the most promising starting point for a development leading to the invention. In selecting the closest prior art, the first consideration is that it should be directed to a similar purpose or effect as the invention or at least belong to the same or a closely related technical field as the claimed invention. In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention.

5.2 Formulation of the objective technical problem

GL/ISPE A13.08.3-A13.08.7 In the second stage, the examiner establishes in an objective way the **technical problem** to be solved. To do this he studies the application (or the patent), the closest prior art and the difference (also called "the **distinguishing feature(s)**" of the claimed invention) in terms of features (either structural or functional) between the claimed invention and the closest prior art, identifies the technical effect resulting from the distinguishing features, and then formulates the technical problem.

The objective technical problem derived in this way may not be what the applicant presented as "the problem" in his application. The latter may require reformulation, since the objective technical problem is based on objectively established facts, in particular appearing in the prior art revealed in the course of the proceedings, which may be different from the prior art of which the applicant was actually aware at the time the application was filed. In particular, the prior art cited in the search report may put the invention in an entirely different perspective from that apparent from reading the application only. Reformulation might lead to the objective technical problem being less ambitious than originally envisaged by the application.

Section G-VII, 5.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

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5.3 Could-would approach

In the third stage the question to be answered is whether there is any teaching in the prior art as a whole that **would** (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves.

GL/ISPE A13.08.8, A13.08.9

5.4 Claims comprising technical and non-technical features

Section G-VII, 5.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

5.4.1 Formulation of the objective technical problem

Section G-VII, 5.4.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

5.4.2 Examples of applying the steps listed in G-VII, 5.4

Illustrative examples can be found in section <u>G-VII, 5.4.2</u>, and subsections G-VII, 5.4.2.1-5.4.2.4, in the Guidelines for Examination in the EPO.

6. Combining pieces of prior art

In the context of the problem-solution approach, it is permissible to combine the disclosure of one or more documents, parts of documents or other pieces of prior art (e.g. a public prior use or unwritten general technical knowledge) with the closest prior art. However, the fact that more than one disclosure must be combined with the closest prior art in order to arrive at a combination of features may be an indication of the presence of an inventive step, e.g. if the claimed invention is not a mere aggregation of features.

Rule 65.1 GL/ISPE 13.12, 13.13

Section G-VII, 6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

7. Combination vs. juxtaposition or aggregation

The invention claimed must normally be considered as a whole. When a claim consists of a "combination of features", it is not correct to argue that the separate features of the combination taken by themselves are known or obvious and that "therefore" the whole subject-matter claimed is obvious. However, where the claim is merely an "aggregation or juxtaposition of features" and not a true combination, it is enough to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step.

GL/ISPE 13.05, 13.14(c), (d)

8. "Ex post facto" analysis

It should be remembered that an invention which at first sight appears obvious might in fact involve an inventive step. Once a new idea has been formulated, it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps. The examiner should be wary of *ex post facto* analysis of this kind. When combining documents cited in the search report, he should always bear in mind that the documents produced in the search have, of necessity, been

GL/ISPE 13.15

obtained with foreknowledge of what matter constitutes the alleged invention. In all cases he should attempt to visualise the overall state of the art confronting the skilled person before the applicant's contribution, and he should seek to make a "real-life" assessment of this and other relevant factors. He should take into account all that is known concerning the background of the invention and give fair weight to relevant arguments or evidence submitted by the applicant, without the benefit of hindsight.

9. Origin of an invention

While the claim should in each case be directed to technical features (and not, for example, merely to an idea), in order to assess whether an inventive step is present it is important for the examiner to bear in mind that an invention may, for example, be based on the following:

- (i) the devising of a solution to a known problem;
- (ii) the arrival at an insight into the cause of an observed phenomenon (the practical use of this phenomenon then being obvious).

Many inventions are of course based on a combination of the above possibilities - e.g. the arrival at an insight and the technical application of that insight may both involve the use of the inventive faculty.

10. Secondary indicators

10.1 Predictable disadvantage; non-functional modification; arbitrary choice

Section G-VII, 10.1, in the Guidelines for Examination in the EPO applies mutatis mutandis.

10.2 Unexpected technical effect; bonus effect

Section G-VII, 10.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

10.3 Long-felt need; commercial success

See ISPE Guidelines 13.16-13.18.

11. Arguments and evidence submitted by the applicant

Section G-VII, 11, in the Guidelines for Examination in the EPO applies mutatis mutandis.

12. Selection inventions

Generally, the principles laid down in section <u>G-VII, 12, in the Guidelines</u> for Examination in the <u>EPO</u> apply *mutatis mutandis*. The subject-matter of selection inventions differs from the closest prior art in that it represents selected sub-sets or sub-ranges. If this selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection, then an inventive step is accepted (this technical effect occurring within the selected range may also be the same effect as attained with the broader known range, but to an unexpected degree). The criterion of "seriously contemplating" mentioned in connection with the test for

novelty of overlapping ranges should not be confused with the assessment of inventive step. For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

The unexpected technical effect must apply to the entire range as claimed. If it occurs in only part of the claimed range, the claimed subject-matter does not solve the specific problem to which the effect relates, but only the more general problem of obtaining, for example, "a further product X" or "a further process Y".

13. Dependent claims; claims in different categories

See ISPE Guidelines 13.19.

14. Examples

See ISPE Guidelines 13.14.

PCT – Part H

Amendments and Corrections

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Chapter I – The right to amend

Chapter <u>H-I</u> deals with the right to amend, while Chapters <u>H-II</u> and <u>H-III</u> deal with the allowability of amendments. Chapter <u>H-IV</u> is dedicated to the rectification of obvious mistakes.

1. Introduction

Notwithstanding the possibility to amend the claims before the IB under <u>Art. 19</u>, an international application may be amended during the <u>PCT Chapter II</u> procedure. There are a number of important aspects to consider.

Firstly, the amendments filed must be such that they can be taken into consideration by the EPO in its capacity as IPEA. The conditions governing timing and formal aspects are explained in <u>GL/PCT-EPO H-I, 2-6</u>.

Any change in the claims, the description or the drawings, other than a rectification of obvious mistakes under <u>Rule 91</u>, a correction under <u>Rule 26</u> or the furnishing of a missing part under <u>Rule 20.5</u>, is considered an amendment. Unless withdrawn or superseded by later amendments, any change considered an amendment must be taken into consideration for the purpose of the international preliminary examination.

Art. 19 Art. 34(2)(b) Rule 66.5 GL/ISPE 20.04

Secondly, amendments must be allowable, which means that they must not:

(i) add to the application subject-matter which was not disclosed in the application as originally filed

Art. 19(2) Art. 34(2)(b)

(ii) introduce other deficiencies (such as lack of clarity in the claims).

GL/ISPE 20.09

2. Amendments before receipt of the search report

There is no right to amend the application until after the international search report has been established. Obvious mistakes, on the other hand, may be corrected (see <u>GL/PCT-EPO H-IV</u>).

3. Amendments prior to the start of international preliminary examination

When filing the demand, the applicant should indicate on Form PCT/IPEA/401 which documents should form the basis for international preliminary examination. These may be:

Art. 19 Art. 34(2)(b) Rule 53.9 Rule 66.1 GL/ISPE 20.01-20.02

the international application as originally filed, or

- amendments to the claims under Art. 19 and/or
- amendments to the claims, the description and/or sequence listings filed as a part thereof and/or the drawings under <u>Art. 34(2)(b)</u>.

The applicant may have filed amended claims under Art. 19 with the International Bureau after receipt of the search report and before the

Rule 53.9(a)

demand was filed. When filing the demand, the applicant may revert to the originally filed claims, reversing his amendments made according to <u>Art. 19</u>. If this is the case, preliminary examination proceeds on the basis of the originally filed set of claims.

Rule 54bis, 69.1(a) PCT AG I 10.010 Amendments and/or arguments filed under <u>Article 34</u> should preferably be filed together with the demand. However, they also have to be taken into account by the EPO as IPEA if they are filed before expiry of the time limit for filing the demand. The applicant may ask for an early start for preliminary examination if amendments and/or arguments are filed before expiry of the time limit for filing the demand (see also <u>GL/PCT-EPO, C-VI, 1</u>).

The examiner should carefully check that the examination is based on the correct set of documents.

4. Further opportunity to submit amendments

Art. 34(2)(b) Rule 66.4 Together with the reply to the WO-ISA, the WO-IPEA or the minutes of a telephone consultation, the applicant has, subject to certain exceptions (see <u>GL/PCT-EPO, C-VII, 1</u>), the opportunity to submit (further) amendments under <u>Art. 34</u> to the claims, description and/or drawings.

Rule 66.4bis

Subsequently filed amendments and/or arguments will be taken into account by the EPO as IPEA only if they are received before the point at which preparation of a written opinion or the IPER has actually started.

For further details, see <u>GL/PCT-EPO C-IV, 1</u> and <u>2</u> and subsections, and <u>GL/PCT-EPO C-VII, 1</u>.

5. Amended sheets

Rule 66.8 GL/ISPE 20.06 Amendments to the claims, the description and the drawings must be made by filing replacement sheets when, on account of the amendments, the replacement sheet differs from the sheets previously filed.

Rule 46.5

If amendments are made to the claims, a complete set of new claims should be filed.

Rule 92.4 GL/ISPE 20.08 The applicant may submit his amendments by fax and there is no need for a confirmation letter, unless the faxed document is illegible. Printed or typed amendments are preferred; handwritten amendments are, in general, not acceptable. Nevertheless, if the handwritten amendments are legible they may – at the discretion of the EPO – be admitted.

PCT AI Annex C, 3ter

If amendments are made to a sequence listing contained in an application filed in electronic form, a sequence listing in electronic form comprising the entire listing with the relevant amendment must be filed.

6. Indication of amendments and their basis

Rule 46.5 Rule 66.8(a) Rule 70.2(c-bis) The applicant is obliged to indicate the basis in the application as originally filed for any amendments filed. If no such basis is indicated, the IPER may

be established as if the amendments had not been made. This is indicated in the IPER under Section I.

If a further WO-IPEA (Form 408) is sent (with respect for the principles set out in <u>GL/PCT-EPO C-IV, 2.2</u>), there should be a similar indication in the WO-IPEA as to which amendments could not be taken into account. Further, the applicant may also be reminded in this WO-IPEA to specify the basis for the amendments which he may file in reply to the WO-IPEA. However, a WO-IPEA whose only content would be a request to indicate the basis for such amendments will not be sent; instead, the IPER is established directly.

Chapter II - Allowability of amendments

1. Introduction

Once the EPO as IPEA has concluded that the amendments can be taken into consideration (see <u>GL/PCT-EPO H-I)</u>, all amended pages (description, claims, drawings) must be examined to see whether they introduce subject-matter not originally disclosed. The examiner should apply the criteria used under <u>Art. 123(2) EPC</u> for the European procedure mutatis mutandis, as indicated below. It is important to note that an amendment which is taken into consideration by the EPO as IPEA is not automatically allowable.

GL/ISPE 20.09

With regard to establishing the WO-IPEA or IPER if any newly filed claim, drawing or part of the description contains amendments which are considered to go beyond the disclosure as originally filed, see GL/PCT-EPO C-III. 4.

2. Allowability of amendments

2.1 Basic principle

The examiner should apply the guidelines of section <u>H-IV, 2.1, in the GL/ISPE 20.12</u> Guidelines for Examination in the EPO mutatis mutandis.

2.2 Content of the application as "originally" filed – general rules

The examiner should apply the guidelines of section <u>H-IV. 2.2.</u> in the Guidelines for Examination in the EPO mutatis mutandis.

2.2.1 Features described in a document cross-referenced in the description

The examiner should apply the guidelines of section H-IV 2.2.1, in the Guidelines for Examination in the EPO *mutatis mutandis*.

2.2.2 Incorporating missing parts completely contained in the priority document

After the filing date, an applicant has the possibility to furnish parts of the application (i.e. part of the description, part of the claims or part or all of the drawings) which were erroneously omitted, and still keep the original filing date.

Rule 20.6

This can be done only within two months from the filing date (or at the invitation of the RO) provided that the priority claim was present at the initial date of filing and only if the applicant can show that the missing parts were completely contained in the priority document. Missing parts which have been accepted under this criterion are considered to be part of the application documents "as originally filed".

Rule 4.18

If the "completely contained" criterion is not met, the application will be redated to the date on which the parts were subsequently furnished unless the applicant withdraws the subsequently furnished parts.

Rule 20.5

If the applicant wants to file missing parts which have no basis in the priority document, the filing date of the application as a whole will be the date on which the parts were subsequently furnished.

2.2.2.1 Test for "completely contained"

The test for "completely contained" is stricter than the test for added subject-matter since it is a test whether the subsequently filed missing part was identical to the corresponding extract in the priority document, or a translation thereof.

Although the Receiving Office (RO) is responsible for the decision on whether the missing parts were completely contained in the priority document, the examiner must check (as far as the documents needed are available) that the decision taken was correct.

If the EPO is the RO, the examiner is only required to check for additional technical content. This entails ensuring that the missing text has been inserted into the description of the application in such a position that it has exactly the same meaning as it had in the priority document.

If the EPO is not the RO, the identity of drawings and the word-for-word identity of parts of the description/claim(s) must also be checked by the examiner (unless the documents needed are not available at this stage).

2.2.2.2 Review by the examiner

Under the PCT a review is not legally provided for in the international phase (and indeed may not even be possible if e.g. the priority document is not available to the ISA), so that the decision by the RO cannot be challenged at this stage. However, any negative finding by the examiner should be indicated in the WO-ISA/IPER and a real review can then take place in the regional phase. See also <u>GL/PCT-EPO B-III, 2.3.3</u>, for the effect on the search and <u>GL/PCT-EPO B-XI, 2.1</u>, for the effect on the WO-ISA. For the effect on examination in <u>Chapter II</u>, see <u>GL/PCT-EPO C-III, 2</u>.

After entry into the regional phase before the EPO (Euro-PCT phase) the applicant can withdraw the later filed parts, in order to avoid re-dating of the application. In this case, it should be noted that amendments which are acceptable under the less strict criterion of Art. 123(2) EPC can always be filed during the Euro-PCT phase.

2.2.3 Sequence listings filed after the date of filing

Rule 13ter.1(c)

Any sequence listing not contained in the international application as filed will – if not allowable as an amendment under <u>Article 34</u> – not form part of the international application.

See <u>GL/PCT-EPO B-VIII, 3.2</u>, for the effect on the search and <u>GL/PCT-EPO B-XI, 7</u>, for the effect on the WO-ISA. For the effect on examination in <u>Chapter II</u>, see <u>GL/PCT-EPO C-VIII, 2.1</u>.

2.2.4 Priority documents

It is not permissible to add to an international application matter present only in the priority document for that application, unless this is done under the provisions of Rule 20.6 (GL/PCT-EPO H-II, 2.2.2). For correction of errors, see GL/PCT-EPO H-IV.

2.2.5 Citation of prior art in the description after the filing date

The examiner should apply the guidelines of section H-IV, 2.2.7, in the GL/ISPE 20.10 Guidelines for Examination in the EPO mutatis mutandis.

2.2.6 Clarification of inconsistencies

The examiner should apply the guidelines of section <u>H-IV</u>, <u>2.2.8</u>, in the <u>GL/ISPE 20.10</u> Guidelines for Examination in the EPO mutatis mutandis.

2.2.7 Trademarks

The examiner should apply the guidelines of section <u>H-IV, 2.2.9</u>, in the Guidelines for Examination in the EPO mutatis mutandis.

2.3 Assessment of "added subject-matter" - examples

The examiner should apply the guidelines of section <u>H-IV, 2.4, in the GL/ISPE 20.13</u> Guidelines for Examination in the EPO *mutatis mutandis*.

3. Compliance of amendments with other PCT requirements

The examiner should apply the guidelines of section <u>H-IV, 4.2, in the GL/ISPE 20.09</u> <u>Guidelines for Examination in the EPO mutatis mutandis.</u>

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Chapter III – Allowability of amendments – examples

1. Introduction

This Chapter provides additional guidance and examples relating to a number of typical situations where compliance with Art. 19(2) and/or Art. 34(2)(b) is an issue. However, it must be borne in mind that the allowability of a specific amendment is ultimately to be decided on a case-by-case basis.

2. Amendments in the description

2.1 Clarification of a technical effect

The examiner should apply the guidelines of section <u>H-V, 2.1</u>, in the <u>GL/ISPE 20.15</u> Guidelines for Examination in the EPO mutatis mutandis.

2.2 Introduction of further examples and new effects

The examiner should apply the guidelines of section <u>H-V, 2.2, in the GL/ISPE 20.16-20.17</u> Guidelines for Examination in the EPO mutatis mutandis.

2.3 Revision of stated technical problem

The examiner should apply the guidelines of section <u>H-V, 2.4, in the *GL/ISPE 20.18*</u> Guidelines for Examination in the EPO *mutatis mutandis*.

2.4 Reference document

The examiner should apply the guidelines of section <u>H-V, 2.5, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

2.5 Alteration, excision or addition of text in the description

The examiner should apply the guidelines of section <u>H-V, 2.6, in the *GL/ISPE 20.19*</u> Guidelines for Examination in the EPO *mutatis mutandis*.

3. Amendments in claims

3.1 Replacement or removal of a feature from a claim

The examiner should apply the guidelines of section <u>H-V, 3.1, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

3.2 Inclusion of additional features

The examiner should apply the guidelines of section <u>H-V, 3.2, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

3.2.1 Intermediate generalisations

The examiner should apply the guidelines of section H-V, 3.2.1, in the Guidelines for Examination in the EPO mutatis mutandis.

3.3 Deletion of part of the claimed subject-matter

The examiner should apply the guidelines of section <u>H-V, 3.3, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

3.4 Broadening of claims

The examiner should apply the guidelines of section <u>H-V, 3.4, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

3.5 Disclaimer disclosed in the application as originally filed

GL/ISPE 20.21

The examiner should apply the guidelines of section <u>H-V, 3.5</u>, in the <u>Guidelines for Examination in the EPO mutatis mutandis</u>.

See also Euro-PCT Guide, point 361.

4. Disclaimers not disclosed in the application as originally filed

4.1 The subject-matter to be excluded is not disclosed in the application as originally filed (so-called undisclosed disclaimers)

The examiner should apply the guidelines of section <u>H-V, 4.1, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

4.2 The subject-matter to be excluded is disclosed in the application as originally filed

The examiner should apply the guidelines of section H-V, 4.2, in the Guidelines for Examination in the EPO mutatis mutandis.

5. Amendments to drawings

It is normally not possible under Art. 34(2)(b) to add completely new drawings to an application, since in most cases a new drawing cannot be unambiguously derivable from the mere text of the description. For the same reasons amendments to drawings should be carefully checked for compliance with Art. 34(2)(b).

For drawings based on the priority document, see <u>GL/PCT-EPO H-II, 2.2.2</u> and subsections.

6. Amendments derived from drawings

The examiner should apply the guidelines of section <u>H-V, 6, in the Guidelines for Examination in the EPO mutatis mutandis.</u>

7. Changes in the title

Rule 5.1, 37 GL/ISPE 16.44 The sole purpose of the title is to inform the public about the technical information disclosed in the application. The title has no bearing on the content of the application as filed. If the examiner establishes or modifies the title, he is not required to gain the approval of the applicant. In view of Rule 5.1, the title may be considered part of the description. The EPO as ISA or IPEA therefore allows the applicant to modify the title.

November 2016 PCT-EPO Guidelines Part H – Chapter IV-1

Chapter IV - Correction of defects and errors

1. Substitute sheets (Rule 26)

If the RO finds defects under Art. 14(1)(a), it invites the applicant to correct them by submitting replacement sheets which will be stamped "SUBSTITUTE SHEET (RULE 26)", and these will retain the original filing date if submitted within the set time limit.

Art. 14
Rule 26
PCT AI Section 325

2. Request for rectification of obvious mistakes in the application documents (Rule 91)

2.1 Introduction

An applicant can request authorisation to rectify obvious mistakes in the international application. Rectification is authorised on condition that:

Rule 91.1(a), (c) GL/ISPE 8.01

- (i) the mistake is obvious to the skilled person, i.e. that something else was intended than what appears in the document concerned, and
- (ii) the rectification is obvious to the skilled person, i.e. that nothing else could have been intended than the proposed correction.

The applicant may submit a request for rectification of an obvious mistake in the description, claims and drawings (not the abstract) of the international application (including amended documents) to the ISA or the IPEA, which is the competent body to authorise or refuse such rectification. If the obvious mistake is related to the request form (PCT/RO/101), it is the RO which authorises or refuses the rectification.

Rule 91.1(b)(ii) and (iii)

2.2 Authorisation or refusal of the request for rectification of obvious mistakes in the application documents

In order to determine whether the request for rectification of obvious mistakes can be authorised, the examiner should check that the time limit for requesting rectification has not expired. The request for rectification can only be considered if it is filed with the competent authority within 26 months from the priority date.

Rule 91.2

If the request is too late, it is refused on that ground.

If the request is in time, the examiner must check whether the requested corrections satisfy the above criteria (i) and (ii) (see <u>GL/PCT-EPO H-IV, 2.1</u>)

- if one or both of the criteria (i) and (ii) are not satisfied, the examiner will not authorise the request and will indicate his reasons.
- if the request is authorised, no reasons need to be given. The fact that a rectification of an obvious mistake has been taken into account will be indicated in the WO-ISA, WO-IPEA (Form 408) or IPER (Form 409) under Section I.

if the request is authorised only in part, the examiner indicates which corrections are not allowable, together with the reasons, and which corrections are allowable. The fact that a rectification of an obvious mistake has been taken into account (in part) will also be indicated in the WO-ISA, WO-IPEA (Form 408) or IPER (Form 409) under Section I.

Rule 91.1 GL/ISPE 17.16 PCT AI Section 607 Authorised replacement pages or sheets for rectification of obvious mistakes under <u>Rule 91</u> are deemed to be part of the international application "as originally filed". These sheets are identified with "RECTIFIED SHEET (RULE 91.1)".

Rule 91.3(d)

If authorisation of a request for rectification is refused, the applicant may request the IB in writing, within two months of the refusal, to publish the refused request together with the reasons for refusal, subject to payment of a special fee.

2.3 Allowability of corrections

The examiner will apply the same criteria in assessing the substantive allowability of proposed corrections according to <u>Rule 91.1</u> as for European applications according to <u>Rule 139 EPC</u> (see <u>GL/EPO H-VI, 2.2.1</u>).

2.4 Examples

The examiner should apply the guidelines of section H-VI, 2.3, in the Guidelines for Examination in the EPO mutatis mutandis.

List of sections amended in 2016 revision

PART B	B-III, 2.3.1	Amended claims or incorporated missing parts: clarified that formal matters which are contrary to the PCT and are called to the attention of the applicant by the receiving Office may be corrected
	B-III, 2.3.3	Clarified the requirements that missing parts filed at a later stage must fulfil in order not to affect the international filing date
	B-IV, 1.2	PCT Direct applications: clarified that under the PCT Direct service the priority application already searched by the EPO may also be an international application
	B-IV, 1.2.1; B-IV, 1.2.2;	Amended in view of the extension of PCT Direct service to all the other receiving Offices
	B-IV, 1.2.3	
	B-VI, 2	Clarified how the EPO treats oral disclosures in the international phase
	B-VII, 2	Lack of unity at the search stage: clarified that also in case of a doublure the applicant will be invited to pay additional fees
	B-VII. 7.1	Admissibility of the protest: clarified the procedure which is applied in case the applicant files as ground for the protest a mere statement of disagreement
	B-VII, 7.2	Review Panel: clarified that the reasoning for upholding the request for payment of the additional fee will address the applicant's arguments to the extent reasonable
	B-VIII, 2	Clarified the procedure followed when the subject-matter of all claims constitutes a subject excluded from the search
	B-XI, 2.1	Clarified the requirements that missing parts filed at a later stage must fulfil in order not to affect the international filing date
	B-XI, 4.1	Restoration of priority: content moved to F-VI, 3.7

	B-XII, 5; B-XII, 7; B-XII, 8;	Clarified that the explanations accompanying the supplementary international search report are not contained in a written opinion
	B-XII, 11	
PART C	<u>C-II, 1</u>	Filing of the demand: clarified the procedure of the filing of the demand
	C-II, 2; C-IV, 2.1	Amended in view of the fact that the EPO is also competent to act as IPEA if the international search was carried out by the Visegrad Patent Institute
	<u>C-II, 4</u>	Applicant's entitlement to file a demand: clarified conditions under which an applicant can file a demand
	<u>C-II, 5</u>	Representation:
		clarified that demand can be filed by a sub-agent;
		clarified procedure in case of multiple applicants
	<u>C-II, 8;</u>	Basis for international preliminary examination: clarified that also a handling fee is due
	<u>C-II, 9</u>	IPEA file: clarified that a file is established only once the conditions under Rule 69.1(a) are fulfilled
	<u>C-II, 10</u>	Correction of deficiencies: clarified procedure in case the EPO as IPEA invites the applicant to correct defects in the demand
	<u>C-II, 11</u>	Payment and refund of fees: clarified conditions for the refund of the examination fee and the handling fee
	<u>C-III. 2</u>	Sheets filed under Rule 20.6 and containing missing parts: clarified that the IPEA will check if the RO applied the "completely contained" criterion correctly
	<u>C-III, 4</u>	Added subject-matter: clarified that the EPO as IPEA will give reasons on why amendments introduce subject-matter not originally disclosed
	C-IV, 4.1	Submissions prompted by a restriction of the search or a declaration that no search is possible: clarified that arguments from the applicant relating to the completeness of the search are treated only in case they are filed as a complaint
	<u>C-VI, 3</u>	Extension of the time limit: clarified that the time limit for filing the demand cannot be extended

	C-IX, 1	Withdrawal of demand under Chapter II: clarified
		Withdrawar of domand under <u>emapterm</u> , claimed
		where the date of the start of the international preliminary examination can be found;
		that conditional withdrawal is not foreseen;
		that the signature of each applicant is required in case of withdrawal
	C-IX, 4	Complaint against the findings at the search stage: the competent department has been specified
PART E	<u>E-II. 1</u>	Amended since IPA (Australia) has become an EPO's PPH partner Office
PART G	G-IV. 3	Date of filing or priority date as effective date: clarified that the applicant can also subsequently furnish under Rule 20.5 missing parts of the claims and/or all or parts of the drawings
	G-IV, 5.1	Prior art pursuant to Rule 64.3: clarified treatment of late-published prior art
	G-IV, 5.2	Co-pending applications: clarified that this sections deals with co- pending applications from the same applicant
	G-VI, 1	Prior art pursuant to <u>Art. 33(2)</u> : clarified that only written disclosures constitute prior art under <u>Art. 33(2)</u>
	G-VII, 5.4.2	New section with examples illustrating the application of the problem-solution approach to claims comprising technical and non-technical features
	G-VII, 10.1	"Ex post facto" analysis: clarified that the inventive step should be assessed "without the benefit of hindsight"
PART H	H-I, 1	Introduction: Clarified which changes to the text of the application are not considered amendments
	H-I, 3	Amendments prior to the start of international preliminary examination: clarified conditions for asking early commencement of the preliminary examination
	H-I, 5	Specified conditions for amending a sequence listing contained in an application filed in electronic form
	H-II, 1	Specified that the EPO applies the criteria for the assessment under Art. 123(2) EPC mutatis mutandis in the PCT procedure
	H-II, 2.2.2	Incorporating missing parts completely contained in the priority document: clarified what can be a missing part of the application

<u>H-III.</u>	<u>,.7</u>	Changes in the title: clarified that the EPO as ISA or IPEA allows modifications to the title by the applicant
H-IV	<u>, 2.2</u>	Authorisation or refusal of the request for rectification of obvious mistakes in the application documents: procedure in case of refusal of the request for rectification added

EDITORIAL CHANGES

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General part	General Part, 1; General Part, 2.1; General Part, 2.2; General Part, 2.3; General Part, 2.7; General Part, 3.1; General Part, 3.2
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PART G	G-II, 1; G-II, 3.1; G-II, 3.2; G-II, 3.3; G-II, 3.4; G-II, 3.5; G-II, 3.6; G-II, 3.7; G-II, 4.1; G-II, 4.2; G-II, 5.2; G-II, 5.3; G-II, 5.4; G-II, 5.5; G-III, 3; G-IV, 1; G-IV, 2; G-IV, 6.2; G-V, 1; G-VI, 2; G-VI, 6; G-VI, 7.1; G-VII, 3.1; G-VII, 5.1; G-VII, 5.2; G-VII, 5.4; G-VII, 5.4.1; G-VII, 5.4.1; G-VII, 6; G-VII, 10.1; G-VII, 10.2; G-VII, 11; G-VII, 12;
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