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**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

**MEETING OF INTERNATIONAL AUTHORITIES
UNDER THE PCT**

**Seventh Session
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**DRAFT PCT INTERNATIONAL SEARCH AND
PRELIMINARY EXAMINATION GUIDELINES:
PROPOSALS BY THE EUROPEAN PATENT OFFICE (EPO)**

Document prepared by the International Bureau

1. The Annexes to this document contain proposals by the EPO for two chapters, designated X and Y, to replace chapter 12 of the draft PCT International Search and Preliminary Examination Guidelines as set out in document PCT/MIA/7/2.

2. *The Meeting of International Authorities is invited to consider the proposals set out in the Annexes to this document.*

[Annex I follows]

ANNEX I

[CHAPTER TO BE ADDED AT THE END OF PART 2]

CHAPTER X - CONTENT OF THE WRITTEN OPINIONS ISSUED BY THE INTERNATIONAL SEARCH AUTHORITY

Introduction

X.01 ~~12.01~~ This chapter covers the content of ~~any~~ written opinion, ~~whether~~ established by the International Searching Authority ~~or the International Preliminary Examining Authority~~. ~~It also covers the content of the international preliminary examination report, which follows a very similar format to a written opinion.~~ The content and the format of the written opinion whether established by the International Searching Authority or by the International Preliminary Examining Authority should be identical. The only exceptions relate to the difference of timing in which the written opinions will be established by the corresponding Authority during the International procedure, e.g. the written opinion by the ISA will be based exclusively on the application documents as originally filed while amendments will have to be considered in most of the written opinions established by the IPEA, there is therefore no need to consider amendments when drafting a WO at search stage.

Article 33(1), 34(2)(c); Rule 43bis.1, 66

X.02 ~~12.02~~ The purpose of a written opinion issued by the ISA is to give a primary indication to the applicant of the defects which the examiner considers to exist in the application so that the applicant can determine the most appropriate course of action, including the possibilities of submitting comments or amendments, before any final report is drawn up having to decide to start the national/regional phase or to file a demand for International Preliminary Examination. Its primary role is to identify whether or not the claimed invention appears to be novel, involve an inventive step (be non-obvious) and be industrially applicable. It will also include opinions on certain other substantive defects, ~~which may be in the application~~ insofar as checked by the authority (Rule 66.2.a (v)), mainly where these affect the ability to determine the novelty, inventive step or industrial application of the invention accurately, and on certain defects in the form of the international application.

~~12.03 The international preliminary examination report follows the same format as a written opinion and, assuming that international preliminary examination is demanded, is established taking into account any amendments or observations filed in response to the written opinions (either of the International Searching Authority or of the International Preliminary Examining Authority) which precede it.~~

Article 33(1), 34(2)(c); Rule 43bis.1, 66

~~*Different Types of Opinion and Report*~~ *Written Opinion of the International Searching Authority*

Rule 43bis, 66.1bis

X.03 ~~12.04~~ A written opinion will be issued by the International Searching Authority together with the international search report. This will normally be treated as the first written opinion of the International Preliminary Examining Authority under Article 34(2) in the event that international preliminary examination is demanded and, as such, the opinion will include an invitation to submit a response, together with a time limit for that response, if the applicant wishes to demand international preliminary examination. However International Preliminary Examining Authorities may notify the International Bureau that this will not be the case for

written opinions issued by specified International Searching Authorities other than themselves. Such notifications are published by the International Bureau in the Gazette.

~~X.04 12.05~~ Many of the Rules that are referred to in this chapter are stated to apply to the International Preliminary Examining Authority conducting an international preliminary examination under Chapter II of the Treaty. However, while this is not explicitly stated in the references, they also apply to the International Searching Authority by virtue of Rule 43bis.1(b).

~~— *Written Opinion(s) of the International Preliminary Examining Authority*~~

Rule 66.4, 66.4, 66.6

~~12.06~~ Written opinions may also be issued by the International Preliminary Examining Authority where international preliminary examination is demanded. The written opinion of the International Searching Authority is usually treated as the first written opinion of the International Preliminary Examining Authority. Although not required, the IPEA may establish further written opinions taking into account arguments or amendments made by the applicant in response to the written opinion issued by the International Searching Authority. Such written opinions will normally offer the applicant a further opportunity to submit amendments or arguments before the international preliminary examination report is established. The International Preliminary Examining Authority may also communicate informally with the applicant over the telephone, in writing, or by personal interview.

~~12.07~~ For international applications where the written opinion of the International Searching Authority is not treated as the first written opinion under Article 34(2), the International Preliminary Examining Authority should:

- ~~— (a) —~~ notify the applicant accordingly in writing (see Chapter 9 [XR]); and
- ~~— (b) —~~ establish a first written opinion as defined in 12.02, which should take into account the content of the written opinion established by the ISA.

~~— *The International Preliminary Examination Report*~~

~~12.08~~ Assuming that international preliminary examination is demanded, an international preliminary examination report (titled “international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)”) is drawn up at the end of the process of examination, taking into account amendments or observations that the applicant has made during the process.

Content of the Written Opinion by ISA

– *Overview of Content*

Rule 43bis, 66.1bis, 66.2(a), 70.2(c) and (d)

X.05 ~~12.09~~ [E-VI-5.10] A Any written opinion of the ISA should usually cover all matters referred to in Rule 66.2 at the exception of Rule 66.2(iv) as no amendment can be filed at this stage of the procedure. Such matters may be:

- (i) whether any of the situations referred to in Article 34(4) (subject matter of the application not required to be examined by the International Preliminary Examining Authority or meaningful opinion on novelty, inventive step or industrial applicability not possible)

because of lack of clarity or because the claims are not adequately supported by the description),

(ii) an apparent failure to meet the criteria of novelty, inventive step or industrial applicability,

(iii) defects in the form or contents of the international application (for example, failure to comply with one or more of the requirements specified in Rules 5 to 11),

~~(iv) amendments which appear to go beyond the disclosure of the international application as filed,~~

(~~v~~iv) an apparent lack of clarity in the claims, the description or the drawings or of support for the claims in the description such as would require some observations to be made in this respect in the international preliminary examination report should such report be established on the basis of the international application without further amendment,

(~~v~~iv) that a claim is directed to an invention on which no international search report has been established, and

(~~vii~~vi) nucleotide and/or amino acid sequence listings not being available in such a form that a meaningful international preliminary examination can be carried out.

– *Form of Opinion*

~~X.06 12.10~~ The Written opinions are of ISA is established in a standard format using form PCT/ISA/xxx [need a new form for this] ~~(for the opinion of an International Searching Authority) or PCT/IPEA/408 (for an opinion of the International Preliminary Examining Authority). International Preliminary Examination Reports (given the title “international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)”) are established using PCT/IPEA/409.~~ Apart from the cover sheet, containing generally bibliographic details and any notification of action that the applicant may be invited to take; this ~~these~~ follows the same format as PCT/IPEA/408 (written opinion of the International Preliminary Examining Authority) and PCT/IPEA/409 (International Preliminary Examination Report), including whichever of the following parts are appropriate to the particular international application:

- (i) Basis of the opinion or report;
- (ii) Priority;
- (iii) Non-establishment of opinion with regard to novelty, inventive step and industrial applicability;
- (iv) Lack of unity of invention;
- (v) Reasoned statement under Rule 66.2(a)(ii) or Article 35(2) with regard to novelty, inventive step or industrial applicability and citations supporting such statement;
- (vi) Certain documents cited;

- (vii) Certain defects in the international application;
- (viii) Certain observations on the international application.

~~— Data~~

Section 109

~~12.11 [E-VI 8.3] The following data (insofar as set out on the front page of the form) should first be included in accordance with Rules 70.3, 70.4, 70.5 and with the relevant Sections of the Administrative Instructions under the PCT:~~

- ~~—— (i) the international application number;~~
- ~~—— (ii) the name of the applicant;~~
- ~~—— (iii) the name of the International Preliminary Examining Authority;~~
- ~~—— (iv) the international filing date;~~
- ~~—— (v) the classification of the subject matter, at least according to the International Patent Classification (IPC);~~
- ~~—— (vi) the claimed priority date;~~
- ~~—— (vii) the applicant's or agent's file reference (composed either of letters or numbers or both, but not exceeding 12 characters).~~

Section 504

~~12.12 The indication of the classification of the subject matter referred to in item (e), above, shall repeat the classification of the subject matter by the International Searching Authority given under Rule 43.3 if the examiner agrees with such classification, or, if the examiner does not agree with that classification, should set forth the classification which the examiner considers to be correct (see Chapter V, "Classification of International Applications," of the PCT International Search Guidelines).~~

~~– Box I - Basis of the Written Opinion~~

Rule 66.2(a)(iv), 70.2(a) and (c)

~~X.07 42.13 [replacing E-VI-5.12] Since the written opinion of the International Searching Authority is drawn up at the same time as the international search report, it will almost always be established on the basis of the application as filed. However, any written opinion drawn up after allowable amendments or corrections have been properly filed (for example a sequence listing complying with the required standards has been furnished on the request of the International Searching Authority or, where the written opinion is established by the International Preliminary Examining Authority, amendments have been filed under Article 19 or 34(2)(b)) should take these into account and note.~~

~~12.14 Any amendment submitted must not add subject matter which goes beyond the disclosure of the international application as originally filed (see paragraph 11.04 [XR]),~~

~~— Examination on Basis of International Application as Filed~~

~~12.15 [AU E 8.2.1] Where all documents examined are as originally filed, only the first check box (i.e. “the international application as originally filed”) in Item 1 of Box I should be marked.~~

– *Substitute Sheets Deemed to Be Part of the Application as Originally Filed*

X.08 ~~12.16~~ [AU-E-8.2.2] Substitute pages or sheets, filed in response to an invitation by the RO to correct defects in the international application, are deemed to be part of the international application “as originally filed”. If the applicant responds to the invitation to correct defects by substituting sheets of the application, these sheets are identified with “SUBSTITUTE SHEET (RULE 26)” stamped on them. Also, substitute pages or sheets for rectification of obvious errors 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)” and “ENTERED DURING CHAPTER I” stamped on them.

~~— Examination on Basis of Amended International Application~~

~~12.17 [AU E 8.2.3] In response to an opinion, an applicant may file amendments with a cover letter. On receipt of these amendments, the IPEA will indicate on the top right hand corner of the substitute sheets the application number and the date of receipt. Note that the date stated by the applicant on the cover letter may differ from the date of receipt of the amendment.~~

~~12.18 Where proper amendments have been made under Article 19, they should be referred to in Box I Item 1 as “Claim(s) pages....as amended under Art 19”. Note that under Article 19 only claims may be amended. These sheets are usually identified by “AMENDED SHEET (ARTICLE 19)”.~~

~~12.19 Where proper amendments have been made under Article 34, these should also be referred to in Box I Item 1 as either “claims pages....filed with Demand” or “claims pages....received on....with the letter of”.~~

~~12.20 The amendments under Article 34 should indicate the dates on the amendments as the “received on” dates and the applicant’s correspondence date as the “with the letter of” date. Superseded amendments should not be included.~~

– *Language Considerations*

Rules 23.1 (b), 48.3(b), 55.2 and 55.3

X.09 ~~12.21~~ With regard to the language, Item 2 of Box I need not be filled if all the elements of the application (~~originally filed sheets and amended sheets, if any~~) were available or furnished to the ISA/~~IPEA~~ in the language in which the international application was filed. Otherwise, an appropriate indication must be checked as to whether the elements were available or furnished to the ISA/~~IPEA~~ in the language which is: (i) the language of a translation furnished for the purposes of international search (under Rule 23.1(b)); (ii) the language of publication of the international application (under Rule 48.3(b)); ~~(iii) the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).~~ For further discussions of language, refer to Chapter 9. [XR]

– *Nucleotide and/or Amino Acid Sequence Listings*

~~X.10 12.22~~ With regard to any nucleotide and/or amino acid sequence listings, an appropriate indication(s) must ~~be~~ ~~me~~ checked as to the examination being drawn on the basis of the sequence listing: (i) contained in the international application in printed form; (ii) filed together with the international application in computer readable form; (iii) furnished subsequently to ISA/IPEA in written form; (iv) furnished subsequently to ISA/IPEA in computer readable form; (v) the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished; (vi) the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished. For further discussions of the nucleotide and/or amino acid sequence listings, refer to Chapter 9. [XR]

— *Amendments Resulting in Gaps in Numbering*

~~12.23~~ Where amendments under Article 19 or 34 have been made which result in cancellation or gaps in the numbering sequence of the description pages, claim numbers, and/or drawing sheets, these must be referred to in Item 4 of Box I of the written opinion and/or report. (Annex C.2 shows a completed example.)

— *Amendments Going Beyond Original Disclosure*

~~12.24~~ Where amendments have been made which go beyond the original disclosure, this is indicated in Box I at Item 5. The particular amendments are identified and brief reasons given in a Supplemental Box sheet(s). *Rule 70.2(e)*

~~12.25~~ Refer to Chapter 11 [XR] for further Article 19/34 considerations.

– [AU-E-8.3]Box II Priority;

~~X.11 12.26~~ This part of the opinion or report is not relevant if the international application does not claim priority. Furthermore, where priority is claimed, but the citations in the international search report were all published before the earliest priority date, it is not necessary to consider whether the priority claim is valid.

~~X.12 12.27~~ Where one or more citations of the international search report were published after the earliest priority date, the validity of that earliest priority date requires checking.

a) where the priority document is one which is in the records of the ISA IPEA, it should be obtained from those records.

Rule 66.7
Ad Inst 421

b) where the priority document is a foreign document and it is not already in the file, the Authority may request a copy of the document from the IB and, if necessary, a translation from the applicant. ~~In the meantime, if the outcome of the examination requires the issuing of an opinion, that opinion should be issued without waiting to obtain the priority document. An appropriate comment should be made under the heading “Additional observations, if necessary:” in Box II of the Written Opinion. If~~ It should be born in mind, however that such a copy may is not be available because the time limit for filing the priority document under Rule 17.1 has not expired or because of non-compliance with this said rule 17.1 by the

applicant, ~~the IPER may be established as if the priority had not been claimed and this is to be indicated in the report.~~ In such cases the fact that the validity of the priority claim may not be able to be established should be taken into consideration by the examiner when drafting the WO of the ISA.

Rule 64.1

X.13 ~~12.28~~ [AU-E-8.3.2] Where the right to priority is invalid, Box II of the Written Opinion or IPER must be completed.

X.14 ~~12.29~~ “Additional observations” relate to Priority considerations only and not to clarity, descriptive support, defects or any other consideration relevant to Box VIII.

- *Box III - Non-establishment of opinion with regard to novelty, inventive step and industrial applicability; [AU-E-8.4]*

Art 17(2)(a)(i)

Rule 67

X.15 ~~12.30~~ This part of the written opinion of the ISA ~~or report~~ explains why an opinion as regards novelty, inventive step and industrial applicability may not have been established for some or all of the subject matter of the international application. For example, Rule 67.1, which applies also to the ISA according to Rule 43bis.1(b), establishes that no International Authority IPEA shall be required to examine certain subject matter within an international application, such as mathematical theories, plant or animal varieties and methods for treatment of the human or animal body. The agreement between WIPO and the International Authorities IPEAs further qualifies this by excepting from exclusion any subject matter, which is examined under national grant procedures. See Chapter [XR] for details of excluded matter.

- *Subject Matter Excluded Under Rule 67.1*

X.16 ~~12.31~~ Where some or all claims are not examined for novelty, inventive step or industrial applicability because they contain excluded subject matter, this observation must be indicated in Item 1 of Box III of the written opinion ~~or examination report~~ of the ISA.

- *Clarity or Support*

Rule 66.2(a)

X.17 ~~12.32~~ [AU-E-8.4.2] Where the description, the claims, or the drawings are so unclear, or the claims are so inadequately supported by the description that no meaningful opinion can be formed on the questions of novelty, inventive step, or industrial applicability of the claimed invention, then the examination may be restricted to those claims that are sufficiently clear and supported by the description to enable an opinion or report to be prepared (see Box III, Item 1, 4th and 5th checkboxes).

X.18 ~~12.33~~ The issues of clarity and descriptive support of claims may be raised separately from considerations of novelty, inventive step and industrial applicability at Box VIII of the written opinion of the ISA ~~or report~~ (see paragraph [XR]).

~~12.34 These matters should not be raised in an international preliminary examination report unless they have already been raised in a written opinion.~~

– *No International Search Made for Some or All Claims*

Art 33(6)

X.19 ~~12.34~~ Where the ISA has not established an international search report and instead issued a declaration under Article 17 (relating to excluded subject matter, clarity, lack of unity, etc), the questions of novelty, inventive step and industrial applicability cannot be addressed since there are no documents to consider under Article 33(6), and such reasoning is added to the ‘non-establishment’ Box of the written opinion/report form of the ISA. ~~(Note that this applies even where Article 34 amendments may have overcome consideration under Article 34(4)(ii)).~~

– *Nucleotide and/or Amino Acid Sequence Listings*

Ad Inst Annex C

X.20 ~~12.35~~ [AU-E-8.4.4] A failure to supply nucleotide and/or amino acid sequence listing information, or have it complying with the Administrative Instructions standards, may preclude any meaningful ~~preliminary~~ examination from being carried out (see Box III Item 2). Refer to Chapter 8 (search stage) and Chapter 9 (examination stage) for discussion of the nucleotide and/or amino acid sequence listings.

– *Box IV - Lack of unity of invention;*

X.21 ~~12.36~~ [AU-E-8.5.1] Irrespective of whether an Invitation to Pay Additional Fees (form PCT/ISA/206 ~~at the international search stage~~) or an ~~Invitation to Restrict or Pay Additional Fees (form PCT/IPEA/405 at the international preliminary examination stage)~~ has been issued, where unity of invention is lacking, this observation must be included in the ~~first~~ written opinion of the ISA ~~and, if still applicable, in subsequent opinions and the report.~~

– *Where Claims Are Not Found to Lack Unity of Invention*

X.22 ~~12.37~~ ~~The~~ A written opinion does not require an observation on lack of unity in Box IV if no lack of unity has been found, ~~except if any entry in Item 1 of Box IV of the IPE has been required to be made (if the unity results from restriction of the claims).~~

Article 34(3), Rule 70.13

X.23 ~~12.38~~ [E-VI-8.7] If the applicant has paid additional fees ~~or has restricted the claims~~ in response to an invitation to do so or if the applicant has failed to respond to the invitation to pay additional fees ~~or restrict the claims~~ (see paragraphs VI-5.5 [XR] to VI-5.9 [XR]), the written opinion of the ISA ~~international preliminary examination report~~ shall so indicate. In addition to the general indication on the first page of the form, the opinion report should also include the indications provided in the supplemental sheet which indicate whether:

- ~~(i) the claims have been restricted;~~
- (i) ~~ii~~ additional fees have been paid without protest;
- (ii) ~~iii~~ additional fees have been paid by the applicant under protest;
- (iii) ~~iv~~ the applicant has not ~~neither restricted the claims nor~~ paid additional fees;

(iv ~~▼~~) the examiner was of the opinion that the international application did not comply with the requirement of unity of invention but decided not to issue an invitation to ~~restrict the claims or~~ pay additional fees.

~~12.39~~ In addition, should the ~~examination international application~~ be restricted to the claims for which the applicant chooses to pay additional fees (case where not all the required additional fees have been paid) ~~as complying with the requirement of unity of invention~~, or which the examiner considers to be the main invention, the written opinion of the ISA ~~report~~ must indicate which parts of the international application were, and which parts were not, the subject of the written opinion of the ISA ~~international preliminary examination~~ (see also paragraph VI-5.6 [XR]).

Rule 68.1, 68.3(c) Section 603

~~X.24 12.40~~ [E-VI-8.8] In the case where the additional fees are paid under protest, the text of the protest, together with the decision thereon must be annexed to the written opinion of the ISA ~~report~~ if the applicant has so requested (see paragraph VI-5.7 [XR]). Where an indication has been given under paragraph VI-8.7(e) [XR], the examiner must also specify the reasons for which the international application was not considered as complying with the requirement of unity of invention.

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

Article 35(2), Rule 43.5(b), 70.6(a) and (b), 70.7(b), 70.8, Section 503, 611

~~X.25 12.41~~ [E-VI-8.10] This statement is as to whether the claims appear to satisfy the criteria of novelty, inventive step (non-obviousness) and industrial applicability (see paragraph VI-1.1 [XR]). The examiner must make this statement in relation to each claim which is to be examined, that is, by the words “YES” or “NO,” or their equivalents in the language of the report. Each such statement must be accompanied by relevant citations, explanations and observations, if any (see paragraph VI-5.10 [XR]). If any of the criteria is not satisfied, the statement shall be negative but if any of the criteria taken separately is satisfied, an indication must be given as to the criterion or criteria so satisfied. The examiner should always cite documents believed to support any negative statement with respect to any of the claimed subject matter. The citation of these documents should be in accordance with Section 503.

Rule 43.5(e), 70.7(b), Section 604

~~X.26 12.42~~ [E-VI-8.11] Explanations should clearly indicate, with reference to the cited documents, the reasons supporting the conclusions that any of the said criteria is or is not satisfied. If only certain passages of the cited documents are relevant or particularly relevant, the examiner should identify these, for example, by indicating the page, column or the lines where such passages appear.

~~X.27 12.42~~ Further guidance on the novelty considerations, inventive step consideration and industrial applicability considerations are provided in Chapters 15, 16 and 17 [XR], respectively.

– *Box VI - Certain documents cited;*

Rule 70.7(b), 70.9, Section 507(a)

~~X.28 12.43~~ [E-VI-8.12] If ~~the examiner has discovered or~~ the international search report has cited, a relevant document, which refers to a non-written disclosure, and the document was

only published on or after the relevant date of the international application, he must indicate in the ~~international preliminary examination report~~ written opinion of the ISA:

- (i) its nature (by placing the letter “O” next to the citation);
- (ii) the date on which the document was made available to the public;
- (iii) the date on which the non-written public disclosure occurred.

Rule 70.7(b), 70.10, Section 507(b)

X.29 ~~42.44~~ [E-VI-8.13] The examiner should also mention, as such, any published application or any patent referred to in the international search report by virtue of Rule 64.3 and should provide for each such published application or patent the following indications:

- (i) its date of publication;
- (ii) its filing date, and its claimed priority date (if any);
- (iii) placing the letter “E” next to the citation.

Rule 70.2(b)

X.30 ~~42.45~~ The report may also indicate that, in the opinion of the International ~~Preliminary Examining~~ Searching Authority, the priority date has not been validly claimed (see also paragraphs VI-6.1 [XR] to VI-6.3 [XR]).

Rule 70.7(b)

X.31 ~~42.46~~ [E-VI-8.14] Details concerning the manner of indicating certain other special categories of documents which may be cited in the ~~international preliminary examination report~~ written opinion of the ISA as well as the manner of indicating the claims to which the documents cited in such report are relevant can be found in Sections 507(c), (d) and (e).

– *Box VII - Certain defects in the international application;*

Rule 70.12

X.32 ~~42.47~~ [E-VI-8.15] If, in the opinion of the examiner, defects exist in the form or contents of the international application, the examiner should include this opinion in the written opinion of the ISA ~~and/or examination report~~ and also indicate the reasons therefore insofar as checked by the ISA (see also paragraphs VI-5.10 [XR] and VI-5.12 [XR]).

– *Box VIII - Certain observations on the international application.*

Rule 70.12

X.33 ~~42.48~~ [E-VI-8.15] If, in the opinion of the examiner, observations made as to the clarity of the claims, the description, and the drawings, or the question whether the claims are fully supported by the description, the examiner should include this opinion in the written opinion of the ISA ~~and/or examination report~~ and also indicate the reasons therefore insofar as checked by the ISA (see also paragraphs VI-5.10 [XR] and VI-5.12 [XR]).

– *Certification*

Rule 70.3, 70.4, 70.14, Section 612

X.34 ~~42.49~~ [E-VI-8.16] When completing the certification of the written opinion of the ISA ~~international preliminary examination report~~, the examiner must indicate the date ~~on which~~

~~the demand for international preliminary examination was submitted and the date on which the written opinion of the ISA report was completed and the name and address of the International Preliminary Examining Searching Authority. These last-mentioned items may either be completed when including the other data or when completing the certification. Every written opinion of the ISA international preliminary examination report must indicate the name of an authorized officer of the International Preliminary Examining Searching Authority responsible for that written opinion report.~~

- *Language of the written opinion of the ISA~~international preliminary examination report and annexes~~*

Rule 48.3(a) and (b), 70.17(a)

~~X.35 42.50~~ [E-VI-8.17] The written opinion of the ISA ~~international preliminary examination report, together with its annexes, if any,~~ must be in the language in which the international application will be ~~was~~ published, or, if the ~~international preliminary~~ examination is carried out on the basis of a translation of the international application, in the language of that translation. An international application filed in Chinese, English, French, German, Japanese, Russian or Spanish is published in that language; an international application filed in any other language is published in the language of a translation into one of these languages.

Rule 66.2(b)

~~X.36 42.54~~ [E-VI-5.13 start] For each ground of objection, the ~~first~~ written opinion of the ISA should indicate the part of the international application which is deficient and the requirement of the PCT which is not met either by referring to specific Articles or Rules, or by other clear explanation; it should also give the reason for any objection.

~~X.37 42.52~~ [E-VI-5.13 middle] If the cited prior art is such as to demonstrate lack of novelty or inventive step in the main claim or claims, and if consequently there is lack of unity of invention between dependent claims, the applicant should be notified of this situation (see also section III-7 [XR]) in the ~~examiner's first~~ written opinion of the ISA. ~~If, in the opinion of the examiner, the response of the applicant (see paragraph VI 6.1 [XR]) does not overcome the objection of lack of unity of invention, the examiner thereafter shall adopt the procedure described in paragraphs VI 5.5 [XR] to VI 5.9 [XR].~~

- *Ensuring written opinion of the ISA ~~Report~~ is of Maximal Use for Later Stages*

~~X.38 42.53~~ [E-VI-5.13 end] Substantive matter in the ~~said~~ written opinion of the ISA should normally be set out first. The opinion should be drafted in such a manner as to facilitate ~~further~~ international preliminary examination of the international application should ~~it be amended~~ a demand to this end be filed, and, in particular, to avoid the need for extensive re-reading ~~should the examiner wish to issue one or more additional written opinions (see paragraphs VI 6.1 [XR] to VI 6.3 [XR]) during International preliminary Examination.~~ Although the examiner is not obliged to do so, he should try to indicate to the applicant those amendments, which would overcome the objection raised in the written opinion of the ISA ~~avoid a negative statement in the international preliminary examination report.~~ In the case of ~~the~~ written opinion of the International Searching Authority, the report should be set out so that it will be easily used by designated Offices in the event that its content is published as an International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty) (see paragraph [XR]).

Invitation to Correct or Amend*Rule 43bis.1(c), 66.2(c) and (d)*

~~X.39~~ ~~12.54~~ [E-VI-5.14, start] The written opinion of the International Searching Authority ~~should~~ must include a notification to the applicant that in the event that he demands international preliminary examination he is invited to file with the International Preliminary Examining Authority his observations, to correct any formal deficiencies and otherwise to submit amendments to the description, claims and drawings before the expiration of the time limit within which he may file his demand (see paragraph [XR]).

~~12.55~~ [E-VI-5.14, middle] ~~Where the written opinion of the International Searching Authority is not treated as the first written opinion under Article 34(2), the first written opinion by the International Preliminary Examining Authority must fix the time limit within which the applicant must reply. The time limit shall be reasonable under the circumstances. It shall normally be two months after the date of the written opinion. In no case shall it be shorter than one month after the said date. It shall be at least two months after the said date where the international search report is transmitted at the same time as the written opinion. In no case shall it be more than three months after the said date.~~

~~X. 40~~ ~~12.56~~ [E-VI-5.14, end] If a demand for International preliminary report is filed, then ~~Failure to reply to the invitation, whether from the written opinion of the International Searching Authority or from a first written opinion actually established by the International Preliminary Examining Authority,~~ may cause the international preliminary examination report to be directly established with a negative determination in relation to certain claims.

Cases Where Partial Written Opinion or No Written Opinion to Be Established

~~X. 41~~ ~~12.57~~ [Based on start of E-VI-5.15] The statement in paragraph [XR], that the written opinion should cover all the relevant issues [XR] to [XR], only sets out the general rule. There may be cases when either the International Searching Authority is not required to perform an ~~international preliminary~~ examination covering the whole of the international application, or else that it is more efficient to defer some matter until later. These may include:

(i) only inventions which have been searched need be examined ~~the subject of international preliminary examination~~ (Rule 66.1(e)) and consequently included within the written opinion;

(ii) cases where the international application relates to subject matter on which the International ~~Preliminary Examining~~ Searching Authority is not required to carry out an ~~international preliminary~~ examination; or

(iii) cases where the claims lack unity of invention;

~~(iv) situations in which a fundamental objection arises, for example, it is clear that certain claims lack novelty and that the claims will have to be drastically recast;~~

~~(v) where the written opinion is established by the International Preliminary Examining Authority, the applicant may have submitted substantial amendments which add subject matter which goes beyond the disclosure of the international application as originally filed.~~

– *Excluded Subject Matter*

Article 34(4)(b), Rule 66.2(a)(i)

~~X. 42 12.58~~ [E-VI-5.11] In the event that the examiner finds that the international application contains subject matter falling within Article 34(4)(a)(i) (that is, subject matter on which the International ~~Preliminary Examining~~ Searching Authority is not required, under Rule 67 and 43bis.1(b), to carry out ~~international preliminary~~ examination) or that all the claims of the international application lack compliance with Article 34(4)(a)(ii) (that is, the description, the claims or the drawings are so unclear, or the claims are so inadequately supported by the description that no meaningful opinion can be formed), he will indicate this defect or these defects in ~~his first~~ the written opinion of the ISA and will not go into the question, in that opinion, whether the claimed invention appears to be novel, appears to involve an inventive step and is industrially applicable. Where any such defect affects only some of the claims, a similar approach should be adopted in respect of such claims. These grounds for limiting the scope of the opinion are considered in detail in chapter [XR]. It should be emphasized that, although the first written opinion is drawn up by the International Searching Authority, the conditions which are considered for this purpose are those which would apply to the International Preliminary Examining Authority according to Rule 43bis.1(b) (though in practice the subject matter on which international preliminary examination is required is the same, for any particular Authority, as that on which an international search report may not be established).

– *Lack of Unity of Invention*

~~X. 43 12.59~~ The written opinion of the ISA should be established for those inventions for which the international search report is established.

~~12.60 In the case where the IPEA decides not to accept the written opinion of other ISAs for the purposes of international preliminary examination, it may be appropriate for the IPEA to issue an “Invitation to Restrict or Pay Additional Fees” (form PCT/IPEA/405).~~

Article 34(3)(c), Rule 68.4, 68.5

~~X. 44 12.61~~ [E-VI-5.6] If the applicant does not comply with the invitation to pay ~~(by not paying the required additional fees or by not restricting the claims either sufficiently or at all),~~ the written opinion of the ISA ~~or international preliminary examination report~~ will have to be established on those parts of the international application which relate to what appears to be the “main invention” or for which additional fees have been paid and the examiner will then indicate the relevant facts in such opinion report. In cases of doubt as to which is the main invention, the invention first mentioned in the claims should be considered the main invention.

~~X. 45 12.62~~ The issues and processes concerning unity of invention, including payment of additional fees under protest, are covered in more detail in Chapter [XR].

– *Dealing With Major Objections First*

~~X. 46 12.63~~ [E-VI-5.15, end] In the event that a fundamental objection arises, ~~including ones which have been introduced by an improper amendment,~~ it may be more appropriate to deal with this objection before making a detailed ~~international preliminary~~ examination; if, for example, the claims need re-casting, it may be pointless to raise objections to the clarity of some dependent claims or to a passage in the description which may have to be amended or even deleted as a consequence. However, if there are other major objections, these should be

dealt with. Generally the examiner should, in ~~at~~ the ~~first~~ written opinion ~~stage~~ of the ISA, seek to make the maximum impact with the broad aim of providing a useful international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty) if the applicant does not demand international preliminary examination and bringing proceedings to a conclusion without any undue delay in order to meet the relevant time limits if international preliminary examination is demanded (see paragraphs VI-3.3 [XR] and VI-3.4 [XR]).

Other Considerations

~~— Citation of certain documents in the international search report~~

~~12.64 [E-VI-7.23] The international search report may cite a document which is not in a working language of the International Searching Authority because the search examiner knows or has strong evidence leading him to suspect (for example, from the drawings, from an abstract, a corresponding patent in a known language, or from a translation produced by some other person familiar with the language of the document) that the document is relevant. The examiner, in his first written opinion, may cite the document on the basis of similar evidence; an abstract or corresponding document in a working language of the International Preliminary Examining Authority, if known to the examiner, will also be cited. If, however, the applicant's response to the first written opinion disputes the relevance of the document and 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 may 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 consider whether it is necessary to send a copy of the translation to the applicant either with an additional written opinion or by way of an informal communication with the applicant.~~

~~— Additional documents taken into consideration in certain cases~~

Article 33(6)

~~12.65 [E-VI-7.24] Although, in principle, international preliminary examination is based on the international search report, the examiner should not be deterred from looking for relevant documents which he personally knows, or has reason to suspect, exist, if he can locate such documents in a short time from material available to him. Such documents shall be considered on the same footing as the documents cited in the international search report. If such an additional document is mentioned by the examiner in a written opinion, a copy of the document will be transmitted to the applicant, if the agreement between the International Preliminary Examining Authority and the International Bureau so provides (see paragraph VI-1.2 [XR]).~~

~~– Contribution to the Art~~

Article 34(2)(b)

~~X. 47 12.66 [E-VI-5.16] When drafting ~~making the full international preliminary examination for the purposes of the first written opinion of the ISA~~, the examiner should concentrate on trying to understand what contribution the invention as defined in the claims makes to the prior art. This should normally be sufficiently clear from the international application as filed. ~~If it is not, the applicant should be invited to elucidate the matter (see paragraph III-4.2 [XR]);~~ but the examiner should not raise an objection of this kind unless he is convinced it is necessary, since to do so might result in the applicant introducing at later stage additional subject matter going beyond the disclosure in the international application as filed (see paragraph VI-4.11 [XR]).~~

– *Inconsistencies Between Description and Claims*

X. 48 ~~42.67~~[E-VI-5.17] While any serious inconsistencies between the claims and description as filed should be objected to (see paragraphs III-4.3 [XR] and III-4.3a [XR]), it should be borne in mind that the claims may also require substantial amendment. In such a situation, the examiner might invite the applicant to amend the description to be in conformity with the final form of the amended claims even though the final form of the main claims may still not be settled. This procedure may help the examiner to expedite the issuance of the international preliminary examination report if demanded. However, it should also be appreciated that the applicant should not be put to unnecessary expense and trouble in providing an amended description if there is any likelihood that the claims will have to be changed again.

– *Recommending Amendments*

X. 49 ~~42.68~~[E-VI-5.18] The examiner should not suggest amendments merely because he thinks they will improve the wording of the description or claims. A pedantic approach is undesirable; what is important is that the meaning of the description and the claims should be clear. It must be emphasized that it is not part of the duty of the examiner to invite the applicant to amend the international application in a particular way to meet an objection, since the drafting of the application is the applicant's responsibility and he should be free to amend in any way he chooses provided that the amendment removes the deficiency and otherwise satisfies the requirements of the PCT. However, it may sometimes be useful if the examiner suggests, at least in general terms, an acceptable form of amendment; but if he does so, he should make it clear that the suggestion is merely for the assistance of the applicant and that other forms of amendment will be considered. The form of the amendment should be as prescribed in Rule 66.8(a).

[Annex II follows]

ANNEX II

[CHAPTER TO BE ADDED IN PART 3]

CHAPTER Y - CONTENT OF THE WRITTEN OPINIONS ISSUED BY THE INTERNATIONAL PRELIMINARY AUTHORITY AND THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Introduction

Y.01 ~~12.01~~ This chapter covers the content of ~~any~~ written opinions, ~~whether~~ established by ~~the International Searching Authority or the International Preliminary Examining Authority~~. It also covers the content of the international preliminary examination report, which follows a very similar format to a written opinion. The content and the format of the written opinion whether established by the International Searching Authority or by the International Preliminary Examining Authority should be identical. The only exceptions relate to the difference of timing in which the written opinions will be established by the corresponding Authority during the International procedure, e.g. the written opinion by the ISA will be based exclusively on the application documents as originally filed while amendments will have to be considered in most of the written opinions established by the IPEA, therefore the Guidelines should stress that amendments should be considered when drafting a WO at IPE stage.

Article 33(1), 34(2)(c); Rule 66

Y.02 ~~12.02~~ The purpose of a written opinion issued by the IPEA is to give a primary indication to the applicant of the defects which the examiner considers to exist in the application so that the applicant can determine the most appropriate course of action, including the possibilities of submitting comments or amendments, before any final International preliminary examination report is drawn up. Its primary role is to identify whether or not the claimed invention appears to be novel, involve an inventive step (be non-obvious) and be industrially applicable. It will also include opinions on certain other substantive defects ~~may be in the application~~ insofar as checked by the Authority (Rule 66.2a), mainly where these affect the ability to determine the novelty, inventive step or industrial application of the invention accurately, and on certain defects in the form of the international application.

Y.03 ~~12.03~~ The international preliminary examination report follows the same format as a written opinion and, assuming that international preliminary examination is demanded, is established taking into account any amendments or observations filed in response to the written opinions (either of the International Searching Authority or of the International Preliminary Examining Authority) which precede it.

Different Types of Written Opinion of the IPEA and International Preliminary Examination Report

~~— *Written Opinion of the International Searching Authority*~~

Rule 43bis, 66.1bis

~~12.04~~ ~~A written opinion will be issued by the International Searching Authority together with the international search report. This will normally be treated as the first written opinion of the International Preliminary Examining Authority under Article 34(2) in the event that international preliminary examination is demanded and, as such, the opinion will include an~~

~~invitation to submit a response, together with a time limit for that response, if the applicant wishes to demand international preliminary examination. However International Preliminary Examining Authorities may notify the International Bureau that this will not be the case for written opinions issued by specified International Searching Authorities other than themselves. Such notifications are published by the International Bureau in the Gazette.~~

~~12.05 Many of the Rules that are referred to in this chapter are stated to apply to the International Preliminary Examining Authority conducting an international preliminary examination under Chapter II of the Treaty. However, while this is not explicitly stated in the references, they also apply to the International Searching Authority by virtue of Rule 43bis.1(b).~~

– *Written Opinion(s) of the International Preliminary Examining Authority*

Rule 66.4, 66.4, 66.6

Y.04 ~~12.06~~ Written opinions may also be issued by the International Preliminary Examining Authority where international preliminary examination is demanded. The written opinion of the International Searching Authority is usually treated as the first written opinion of the International Preliminary Examining Authority. Although not required, the IPEA may establish further written opinions taking into account arguments or amendments made by the applicant in response to the written opinion issued by the International Searching Authority. Such written opinions will normally offer the applicant a further opportunity to submit amendments or arguments before the international preliminary examination report is established. The International Preliminary Examining Authority may also communicate informally with the applicant over the telephone, in writing, or by personal interview.

Y.05 ~~12.07~~ For international applications where the written opinion of the International Searching Authority is not treated as the first written opinion under Article 34(2), the International Preliminary Examining Authority should:

- (a) notify the applicant accordingly in writing (see Chapter 9 [XR]); and
- (b) establish a first written opinion as defined in 12.02, which should take into account the content of the written opinion established by the ISA.

– *The International Preliminary Examination Report*

Y.06 ~~12.08~~ Assuming that international preliminary examination is demanded, an international preliminary examination report (titled “international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)”) is drawn up at the end of the process of examination, taking into account amendments or observations that the applicant has made during the process.

Content of the Written Opinion of the IPEA or International Preliminary Examination Report

– *Overview of Content*

Rule ~~43bis~~, 66.1bis, 66.2(a), 70.2(c) and (d)

Y.07 ~~12.09~~ [E-VI-5.10] ~~Any~~ written opinion should usually cover all matters referred to in Rule 66.2. Such matters may be:

(i) whether any of the situations referred to in Article 34(4) (subject matter of the application not required to be examined by the International Preliminary Examining Authority or meaningful opinion on novelty, inventive step or industrial applicability not possible because of lack of clarity or because the claims are not adequately supported by the description),

(ii) an apparent failure to meet the criteria of novelty, inventive step or industrial applicability,

(iii) defects in the form or contents of the international application (for example, failure to comply with one or more of the requirements specified in Rules 5 to 11),

(iv) amendments which appear to go beyond the disclosure of the international application as filed,

(v) an apparent lack of clarity in the claims, the description or the drawings or of support for the claims in the description such as would require some observations to be made in this respect in the international preliminary examination report should such report be established on the basis of the international application without further amendment,

(vi) that a claim is directed to an invention on which no international search report has been established, and

(vii) nucleotide and/or amino acid sequence listings not being available in such a form that a meaningful international preliminary examination can be carried out.

– *Form of Opinion or Report*

Y.08 12.10 Written opinions of the IPEA are established in a standard format using form PCT/ISA/xxx [need a new form for this] (for the opinion of an International Searching Authority) or PCT/IPEA/408 (for an opinion of the International Preliminary Examining Authority). International Preliminary Examination Reports (given the title “international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)”) are established using PCT/IPEA/409. Apart from the cover sheet, containing generally bibliographic details and any notification of action that the applicant may be invited to take, these follow the same format as PCT/ISA/xxx [need a new form for this] (for the opinion of an International Searching Authority), including whichever of the following parts are appropriate to the particular international application:

- (i) Basis of the opinion or report;
- (ii) Priority;
- (iii) Non-establishment of opinion with regard to novelty, inventive step and industrial applicability;
- (iv) Lack of unity of invention;
- (v) Reasoned statement under Rule 66.2(a)(ii) or Article 35(2) with regard to novelty, inventive step or industrial applicability and citations supporting such statement;
- (vi) Certain documents cited;

- (vii) Certain defects in the international application;
- (viii) Certain observations on the international application.

— *Data*

Section 109

~~12.11 [E-VI 8.3] The following data (insofar as set out on the front page of the form) should first be included in accordance with Rules 70.3, 70.4, 70.5 and with the relevant Sections of the Administrative Instructions under the PCT:~~

- ~~—— (i) the international application number;~~
- ~~—— (ii) the name of the applicant;~~
- ~~—— (iii) the name of the International Preliminary Examining Authority;~~
- ~~—— (iv) the international filing date;~~
- ~~—— (v) the classification of the subject matter, at least according to the International Patent Classification (IPC);~~
- ~~—— (vi) the claimed priority date;~~
- ~~—— (vii) the applicant's or agent's file reference (composed either of letters or numbers or both, but not exceeding 12 characters).~~

Section 504

~~12.12 The indication of the classification of the subject matter referred to in item (e), above, shall repeat the classification of the subject matter by the International Searching Authority given under Rule 43.3 if the examiner agrees with such classification, or, if the examiner does not agree with that classification, should set forth the classification which the examiner considers to be correct (see Chapter V, "Classification of International Applications," of the PCT International Search Guidelines).~~

– *Box I - Basis of the Written Opinion*

Rule 66.2(a)(iv), 70.2(a) and (c)

~~Y.09 12.13 [replacing E-VI-5.12] Since the written opinion of the International Searching Authority is drawn up at the same time as the international search report, it will almost always be established on the basis of the application as filed. However, a~~ Any written opinion drawn up after allowable amendments or corrections have been properly filed (for example a sequence listing complying with the required standards has been furnished on the request of the International Searching Authority or, where the written opinion is established by the International Preliminary Examining Authority, amendments have been filed under Article 19 or 34(2)(b)) should take these into account and note.

Y.10 12.14 Any amendment submitted must not add subject matter which goes beyond the disclosure of the international application as originally filed (see paragraph 11.04 [XR]),

– *Examination on Basis of International Application as Filed*

Y.11 ~~42.15~~ [AU-E-8.2.1] Where all documents examined are as originally filed, only the first check box (i.e. “the international application as originally filed”) in Item 1 of Box I should be marked.

– *Substitute Sheets Deemed to Be Part of the Application as Originally Filed*

Y.12 ~~42.16~~ [AU-E-8.2.2] Substitute pages or sheets, filed in response to an invitation by the RO to correct defects in the international application, are deemed to be part of the international application “as originally filed”. If the applicant responds to the invitation to correct defects by substituting sheets of the application, these sheets are identified with “SUBSTITUTE SHEET (RULE 26)” stamped on them. Also, substitute pages or sheets for rectification of obvious errors 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)” and “ENTERED DURING CHAPTER I” stamped on them.

– *Examination on Basis of Amended International Application*

Y.13 ~~42.17~~ [AU-E-8.2.3] In response to an opinion, an applicant may file amendments with a cover letter. On receipt of these amendments, the IPEA will indicate on the top right hand corner of the substitute sheets the application number and the date of receipt. Note that the date stated by the applicant on the cover letter may differ from the date of receipt of the amendment.

Y.14 ~~42.18~~ Where ~~proper~~ allowable amendments have been made under Article 19, they should be referred to in Box I Item 1 as “Claim(s) pages... as amended under Art 19”. Note that under Article 19 only claims may be amended. These sheets are usually identified by “AMENDED SHEET (ARTICLE 19)”.

Y.15 ~~42.19~~ Where ~~proper~~ allowable amendments have been made under Article 34, these should also be referred to in Box I Item 1 as either “claims pages... filed with Demand” or “claims pages... received on... with the letter of...”.

Y.16 ~~42.20~~ The amendments under Article 34 should indicate the dates on the amendments as the “received on” dates and the applicant’s correspondence date as the “with the letter of” date. Superseded amendments should not be included.

– *Language Considerations*

Rules 23.1(b), 48.3(b), 55.2 and 55.3

Y.17 ~~42.21~~ With regard to the language, Item 2 of Box I need not be filled if all the elements of the application (originally filed sheets and amended sheets, if any) were available or furnished to the ISA/IPEA in the language in which the international application was filed. Otherwise, an appropriate indication must be checked as to whether the elements were available or furnished to the ISA/IPEA in the language which is: ~~(i) the language of a translation furnished for the purposes of international search (under Rule 23.1(b)); (ii) the language of publication of the international application (under Rule 48.3(b)); (iii) the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).~~ For further discussions of language, refer to Chapter 9. [XR]

– *Nucleotide and/or Amino Acid Sequence Listings*

Y.18 ~~42.22~~ With regard to any nucleotide and/or amino acid sequence listings, an appropriate indication(s) must ~~not be~~ checked as to the examination being drawn on the basis of the sequence listing: (i) contained in the international application in printed form; (ii) filed together with the international application in computer readable form; (iii) furnished subsequently to ISA/IPEA in written form; (iv) furnished subsequently to ISA/IPEA in computer readable form; (v) the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished; (vi) the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished. For further discussions of the nucleotide and/or amino acid sequence listings, refer to Chapter 9. [XR]

– *Amendments Resulting in Gaps in Numbering*

Y.19 ~~42.23~~ Where amendments under Article 19 or 34 have been made which result in cancellation or gaps in the numbering sequence of the description pages, claim numbers, and/or drawing sheets, these must be referred to in Item 4 of Box I of the written opinion and/or report. (Annex C.2 shows a completed example.)

– *Amendments Going Beyond Original Disclosure*

Rule 70.2(c)

Y.20 ~~42.24~~ Where amendments have been made which go beyond the original disclosure, this is indicated in Box I at Item 5. The particular amendments are identified and brief reasons given in a Supplemental Box sheet(s).

Y.21 ~~42.25~~ Refer to Chapter 11 [XR] for further Article 19/34 considerations.

– *[AU-E-8.3]Box II Priority;*

Y.22 ~~42.26~~ This part of the opinion or report is not relevant if the international application does not claim priority. Furthermore, where priority is claimed, but the citations in the international search report were all published before the earliest priority date, it is not necessary to consider whether the priority claim is valid.

Y.23 ~~42.27~~ Where one or more citations of the international search report were published after the earliest priority date, the validity of that earliest priority date requires checking.

(a) where the priority document is one which is in the records of the IPEA, it should be obtained from those records.

Rule 66.7

Ad Inst 421

(b) where the priority document is a foreign document and it is not already in the file, the Authority may request a copy of the document from the IB and, if necessary, a translation from the applicant. In the meantime, if the outcome of the examination requires the issuing of an opinion, that opinion should be issued without waiting to obtain the priority document. An appropriate comment should be made under the heading “Additional observations, if necessary:” in Box II of the Written Opinion. If such a copy is not available because of non-compliance with Rule 17.1 by the applicant, the IPER may be established as if the priority had not been claimed and this is to be indicated in the report.

Rule 64.1

Y.24 ~~42.28~~ [AU-E-8.3.2] Where the right to priority is invalid, Box II of the Written Opinion or IPER must be completed.

Y.25 ~~42.29~~ “Additional observations” relate to Priority considerations only and not to clarity, descriptive support, defects or any other consideration relevant to Box VIII.

- *Box III - Non-establishment of opinion with regard to novelty, inventive step and industrial applicability;[AU-E-8.4]*

Art 17(2)(a)(i)-34.4(a)(i)
Rule 67

Y.26 ~~42.30~~ This part of the opinion or report explains why an opinion as regards novelty, inventive step and industrial applicability may not have been established for some or all of the subject matter of the international application. For example, Rule 67.1 establishes that no IPEA shall be required to examine certain subject matter within an international application, such as mathematical theories, plant or animal varieties and methods for treatment of the human or animal body. The agreement between WIPO and IPEAs further qualifies this by excepting from exclusion any subject matter, which is examined under national grant procedures. See Chapter [XR] for details of excluded matter.

- *Subject Matter Excluded Under Rule 67.1*

Y.27 ~~42.31~~ Where some or all claims are not examined for novelty, inventive step or industrial applicability because they contain excluded subject matter, this observation must be indicated in Item 1 of Box III of the written opinion or examination report.

- *Clarity or Support*

Rule 66.2(a)

Y.28 ~~42.32~~ [AU-E-8.4.2] Where the description, the claims, or the drawings are so unclear, or the claims are so inadequately supported by the description that no meaningful opinion can be formed on the questions of novelty, inventive step, or industrial applicability of the claimed invention, then the examination may be restricted to those claims that are sufficiently clear and supported by the description to enable an opinion or report to be prepared (see Box III, Item 1, 4th and 5th checkboxes).

Y.29 ~~42.33~~ The issues of clarity and descriptive support of claims may be raised separately from considerations of novelty, inventive step and industrial applicability at Box VIII of the opinion or report (see paragraph [XR]).

Y.30 ~~42.34~~ These matters should not be raised in an international preliminary examination report unless they have already been raised in a written opinion.

- *No International Search Made for Some or All Claims*

Art 33(6)

Y.31 ~~42.34~~ Where the ISA has not established an international search report and instead issued a declaration under Article 17 (relating to excluded subject matter, clarity, lack of unity, etc), the questions of novelty, inventive step and industrial applicability cannot be addressed since there are no documents to consider under Article 33(6), and such reasoning is added to the ‘non-establishment’ Box of the opinion/report form. (Note that this applies even

where Article 34 or 19 amendments may have overcome consideration under Article 34(4)(ii).

– *Nucleotide and/or Amino Acid Sequence Listings*

Ad Inst Annex C

Y.32 ~~12.35~~ [AU-E-8.4.4] A failure to supply nucleotide and/or amino acid sequence listing information, or have it complying with the Administrative Instructions standards, may preclude any meaningful preliminary examination from being carried out (see Box III Item 2). Refer to ~~Chapter 8 (search stage) and~~ Chapter 9 (examination stage) for discussion of the nucleotide and/or amino acid sequence listings.

– *Box IV - Lack of unity of invention;*

Y.33 ~~12.36~~ [AU-E-8.5.1] Irrespective of whether an Invitation to Pay Additional Fees (form PCT/ISA/206 at the international search stage) or an Invitation to Restrict or Pay Additional Fees (form PCT/IPEA/405 at the international preliminary examination stage) has been issued, where unity of invention is lacking, this observation must be included in the first written opinion (generally the WO of the ISA) and, if still applicable, in subsequent written opinions of the IPEA and the international preliminary examination report.

– *Where Claims Are Not Found to Lack Unity of Invention*

Y.34 ~~12.37~~ A written opinion does not require an observation on lack of unity in Box IV if no lack of unity has been found, except if any entry in Item 1 of Box IV of the IPE has been required to be made (if the unity results from restriction of the claims).

Article 34(3), Rule 70.13

Y.35 ~~12.38~~ [E-VI-8.7] If the applicant has paid additional fees or has restricted the claims in response to an invitation to do so or if the applicant has failed to respond to the invitation to pay additional fees or restrict the claims (see paragraphs VI-5.5 [XR] to VI-5.9 [XR]), the international preliminary examination report shall so indicate. In addition to the general indication on the first page of the form, the report should also include the indications provided in the supplemental sheet which indicate whether:

- (i) the claims have been restricted;
- (ii) additional fees have been paid without protest;
- (iii) additional fees have been paid by the applicant under protest;
- (iv) the applicant has neither restricted the claims nor paid additional fees;
- (v) the examiner was of the opinion that the international application did not comply with the requirement of unity of invention but decided not to issue an invitation to restrict the claims or pay additional fees.

~~12.39~~ In addition, should the international application be restricted to the claims which the applicant chooses as complying with the requirement of unity of invention, or which the examiner considers to be the main invention, the international preliminary examination report must indicate which parts of the international application were, and which parts were not, the subject of international preliminary examination (see also paragraph VI-5.6 [XR]).

Rule 68.1, 68.3(c) Section 603

Y.36 ~~42.40~~ [E-VI-8.8] In the case where the additional fees are paid under protest, the text of the protest, together with the decision thereon, must be annexed to the report if the applicant has so requested (see paragraph VI-5.7 [XR]). Where an indication has been given under paragraph VI-8.7(e) [XR], the examiner must also specify the reasons for which the international application was not considered as complying with the requirement of unity of invention.

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

Article 35(2), Rule 43.5(b), 70.6(a) and (b), 70.7(b), 70.8, Section 503, 611

Y.37 ~~42.41~~ [E-VI-8.10] This statement is as to whether the claims appear to satisfy the criteria of novelty, inventive step (non-obviousness) and industrial applicability (see paragraph VI-1.1 [XR]). The examiner must make this statement in relation to each claim which is to be examined, that is, by the words “YES” or “NO,” or their equivalents in the language of the report. Each such statement must be accompanied by relevant citations, explanations and observations, if any (see paragraph VI-5.10 [XR]). If any of the criteria is not satisfied, the statement shall be negative but if any of the criteria taken separately is satisfied, an indication must be given as to the criterion or criteria so satisfied. The examiner should always cite documents believed to support any negative statement with respect to any of the claimed subject matter. The citation of these documents should be in accordance with Section 503.

Rule 43.5(e), 70.7(b), Section 604

Y.38 ~~42.42~~ [E-VI-8.11] Explanations should clearly indicate, with reference to the cited documents, the reasons supporting the conclusions that any of the said criteria is or is not satisfied. If only certain passages of the cited documents are relevant or particularly relevant, the examiner should identify these, for example, by indicating the page, column or the lines where such passages appear.

Y.39 ~~42.42~~ Further guidance on the novelty considerations, inventive step consideration and industrial applicability considerations are provided in Chapters 15, 16 and 17 [XR], respectively.

- *Box VI - Certain documents cited;*

Rule 70.7(b), 70.9, Section 507(a)

Y.40 ~~42.43~~ [E-VI-8.12] If the examiner has discovered or the international search report has cited, a relevant document which refers to a non-written disclosure, and the document was only published on or after the relevant date of the international application, he must indicate in the international preliminary examination report:

- (i) its nature (by placing the letter “O” next to the citation);
- (ii) the date on which the document was made available to the public;
- (iii) the date on which the non-written public disclosure occurred.

Rule 70.7(b), 70.10, Section 507(b)

Y.41 ~~42.44~~ [E-VI-8.13] The examiner should also mention, as such, any published application or any patent referred to in the report by virtue of Rule 64.3 and should provide for each such published application or patent the following indications:

- (i) its date of publication;
- (ii) its filing date, and its claimed priority date (if any);
- (iii) placing the letter “E” next to the citation.

Rule 70.2(b)

Y.42 ~~12.45~~ The international preliminary examination report may also indicate that, in the opinion of the International Preliminary Examining Authority, the priority date has not been validly claimed (see also paragraphs VI-6.1 [XR] to VI-6.3 [XR]).

Rule 70.7(b)

Y.43 ~~12.46~~ [E-VI-8.14] Details concerning the manner of indicating certain other special categories of documents which may be cited in the international preliminary examination report as well as the manner of indicating the claims to which the documents cited in such report are relevant can be found in Sections 507(c), (d) and (e).

– *Box VII - Certain defects in the international application;*

Rule 70.12

Y.44 ~~12.47~~ [E-VI-8.15] If, in the opinion of the examiner, defects exist in the form or contents of the international application, the examiner should include this opinion in the written opinion of the IPEA and/or international preliminary examination report and also indicate the reasons therefore insofar as checked by the IPEA (see also paragraphs VI-5.10 [XR] and VI-5.12 [XR]).

– *Box VIII - Certain observations on the international application.*

Rule 70.12

Y.45 ~~12.48~~ [E-VI-8.15] If, in the opinion of the examiner, observations made as to the clarity of the claims, the description, and the drawings, or the question whether the claims are fully supported by the description, the examiner may include this opinion in the written opinion of the IPEA and/or international preliminary examination report and also indicate the reasons therefore insofar as checked by the IPEA (see also paragraphs VI-5.10 [XR] and VI-5.12 [XR]).

– *Certification*

Rule 70.3, 70.4, 70.14, Section 612

Y.46 ~~12.49~~ [E-VI-8.16] When completing the certification of the international preliminary examination report, the examiner must indicate the date on which the demand for international preliminary examination was submitted and the date on which the report was completed and the name and address of the International Preliminary Examining Authority. These last-mentioned items may either be completed when including the other data or when completing the certification. Every international preliminary examination report must indicate the name of an authorized officer of the International Preliminary Examining Authority responsible for that report.

– *Language of the international preliminary examination report and annexes*

Rule 48.3(a) and (b), 55.2, 70.17(a)

Y.47 ~~12.50~~ [E-VI-8.17] The international preliminary examination report, together with its annexes, if any, must be in the language in which the international application was published,

or, if the international preliminary examination is carried out on the basis of a translation of the international application, in the language of that translation. An international application filed in Chinese, English, French, German, Japanese, Russian or Spanish is published in that language; an international application filed in any other language is published in the language of a translation into one of these languages.

Rule 66.2(b)

Y.48 ~~42.51~~ [E-VI-5.13 start] For each ground of objection, the first written opinion (in general this will be the WO of the ISA) should indicate the part of the international application which is deficient and the requirement of the PCT which is not met either by referring to specific Articles or Rules, or by other clear explanation; it should also give the reason for any objection.

Y.49 ~~42.52~~ [E-VI-5.13 middle] If the cited prior art is such as to demonstrate lack of novelty or inventive step in the main claim or claims, and if consequently there is lack of unity of invention between dependent claims, the applicant should be notified of this situation (see also section III-7 [XR]) in the ~~examiner's~~ first written opinion (in general this will be the WO of the ISA). If, in the opinion of the examiner, the response of the applicant (see paragraph VI-6.1 [XR]) does not overcome the objection of lack of unity of invention, the examiner thereafter shall adopt the procedure described in paragraphs VI-5.5 [XR] to VI-5.9 [XR].

– *Ensuring Report is of Maximal Use for Later Stages*

Y.50 ~~42.53~~ [E-VI-5.13 end] Substantive matter in the said opinion should normally be set out first. The opinion should be drafted in such a manner as to facilitate ~~further international preliminary~~ examination of the international application should it be amended, and, in particular, to avoid the need for extensive re-reading should the examiner wish to issue one or more additional written opinions (see paragraphs VI-6.1 [XR] to VI-6.3 [XR]). Although the examiner is not obliged to do so, he should try to indicate to the applicant those amendments which would avoid a negative statement in the international preliminary examination report. ~~In the case of the written opinion of the International Searching Authority, the report should be set out so that it will be easily used by designated Offices in the event that its content is published as an International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty) (see paragraph [XR]).~~

Invitation to Correct or Amend

Rule ~~43bis.1(c)~~, 66.2(c) and (d)

~~12.54~~ [E-VI-5.14, start] ~~The written opinion of the International Searching Authority should include a notification to the applicant that in the event that he demands international preliminary examination he is invited to file with the International Preliminary Examining Authority his observations, to correct any formal deficiencies and otherwise to submit amendments to the description, claims and drawings before the expiration of the time limit within which he may file his demand (see paragraph [XR]).~~

Y.51 ~~42.55~~ [E-VI-5.14, middle] Where the written opinion of the International Searching Authority is not treated as the first written opinion under Article 34(2), the first written opinion by the International Preliminary Examining Authority must fix the time limit within which the applicant must reply. The time limit shall be reasonable under the circumstances. It shall normally be two months after the date of the written opinion. In no case shall it be shorter than one month after the said date. It shall be at least two months after the said date

where the international search report is transmitted at the same time as the written opinion. In no case shall it be more than three months after the said date.

~~Y.52 42.56~~ [E-VI-5.14, end] Failure to reply to the invitation, ~~whether from the written opinion of the International Searching Authority or from a first or subsequent written opinion actually established by the International Preliminary Examining Authority,~~ may cause the international preliminary examination report to be established with a negative determination in relation to certain claims.

Cases Where Partial Written Opinion or No Written Opinion to Be Established

~~Y.53 42.57~~ [Based on start of E-VI-5.15] The statement in paragraph [XR], that the written opinion should cover all the relevant issues [XR] to [XR], only sets out the general rule. There may be cases when ~~either the International Preliminary Examination Authority is not required to perform an international preliminary examination covering the whole of the international application, or else that it is more efficient to defer some matter until later.~~ These may include:

- (i) only inventions which have been searched need be the subject of international preliminary examination (Rule 66.1(e)) and consequently included within the written opinion;
- (ii) cases where the international application relates to subject matter on which the International Preliminary Examining Authority is not required to carry out an international preliminary examination;
- (iii) cases where the claims lack unity of invention;
- (iv) situations in which a fundamental objection arises, for example, it is clear that certain claims lack novelty and that the claims will have to be drastically recast; or
- (v) ~~where the written opinion is established by the International Preliminary Examining Authority,~~ the applicant may have submitted substantial amendments which add subject matter which goes beyond the disclosure of the international application as originally filed.

– *Excluded Subject Matter*

Article 34(4)(b), Rule 66.2(a)(i)

~~Y.54 42.58~~ [E-VI-5.11] In the event that the examiner finds that the international application contains subject matter falling within Article 34(4)(a)(i) (that is, subject matter on which the International Preliminary Examining Authority is not required, under Rule 67, to carry out international preliminary examination) or that all the claims of the international application lack compliance with Article 34(4)(a)(ii) (that is, the description, the claims or the drawings are so unclear, or the claims are so inadequately supported by the description that no meaningful opinion can be formed), he will indicate this defect or these defects in his first written opinion (in general the WO of the ISA) and will not go into the question, in that opinion, whether the claimed invention appears to be novel, appears to involve an inventive step and is industrially applicable. Where any such defect affects only some of the claims, a similar approach should be adopted in respect of such claims. These grounds for limiting the scope of the opinion are considered in detail in chapter [XR]. ~~It should be emphasized that, although the first written opinion is drawn up by the International Searching Authority, the conditions which are considered for this purpose are those which would apply to the~~

~~International Preliminary Examining Authority (though in practice the subject matter on which international preliminary examination is required is the same, for any particular Authority, as that on which an international search report may not be established).~~

– *Lack of Unity of Invention*

~~12.59 The written opinion of the ISA should be established for those inventions for which the international search report is established.~~

Y.55 ~~12.60~~ In the case where the IPEA decides not to accept the written opinion of other ISAs for the purposes of international preliminary examination, it may be appropriate for the IPEA to issue an “Invitation to Restrict or Pay Additional Fees” (form PCT/IPEA/405).

Article 34(3)(c), Rule 68.4, 68.5

Y.56 ~~12.61~~ [E-VI-5.6] If the applicant does not comply with the invitation (by not paying the additional fees or by not restricting the claims either sufficiently or at all), the written opinion of the IPEA or international preliminary examination report will have to be established on those parts of the international application which relate to what appears to be the “main invention” and the examiner will then indicate the relevant facts in such report. In cases of doubt as to which is the main invention, the invention first mentioned in the claims should be considered the main invention.

Y.57 ~~12.62~~ The issues and processes concerning unity of invention, including payment of additional fees under protest, are covered in more detail in Chapter [XR].

– *Dealing With Major Objections First*

Y.58 ~~12.63~~ [E-VI-5.15, end] In the event that a fundamental objection arises, including ones which have been introduced by an ~~improper~~ amendment, it may be more appropriate to deal with this objection before making a detailed international preliminary examination; if, for example, the claims need re-casting, it may be pointless to raise objections to the clarity of some dependent claims or to a passage in the description which may have to be amended or even deleted as a consequence. However, if there are other major objections, these should be dealt with. Generally the examiner should, at the first written opinion stage (in general this will be the WO of the ISA), seek to make the maximum impact with the broad aim of providing a useful ~~international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)~~ if the applicant does not demand international preliminary examination basis for the rest of the international procedure and bringing proceedings to a conclusion without any undue delay in order to meet the relevant time limits if international preliminary examination is demanded (see paragraphs VI-3.3 [XR] and VI-3.4 [XR]).

Other Considerations

– *Citation of certain documents in the international search report*

Y.59 ~~12.64~~ [E-VI-7.23] The international search report may cite a document which is not in a working language of the International Searching Authority because the search examiner knows or has strong evidence leading him to suspect (for example, from the drawings, from an abstract, a corresponding patent in a known language, or from a translation produced by some other person familiar with the language of the document) that the document is relevant. The examiner, in his first written opinion (in general this will be the WO of the ISA), may cite the document on the basis of similar evidence; an abstract or corresponding document in a

working language of the International Preliminary Examining Authority, if known to the examiner, will also be cited. If, however, the applicant's response to the first written opinion disputes the relevance of the document and gives specific reasons, the examiner of the IPEA 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 may 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 consider whether it is necessary to send a copy of the translation to the applicant either with an additional written opinion or by way of an informal communication with the applicant.

– *Additional documents taken into consideration in certain cases*

Article 33(6)

Y.60 ~~42.65~~ [E-VI-7.24] Although, in principle, international preliminary examination is based on the international search report, the examiner should not be deterred from looking for relevant documents which he personally knows, or has reason to suspect, exist, if he can locate such documents in a short time from material available to him. Such documents shall be considered on the same footing as the documents cited in the international search report. If such an additional document is mentioned by the examiner in a written opinion of the IPEA, a copy of the document will be transmitted to the applicant, if the agreement between the International Preliminary Examining Authority and the International Bureau so provides (see paragraph VI-1.2 [XR]).

– *Contribution to the Art*

Article 34(2)(b)

Y.61 ~~42.66~~ [E-VI-5.16] When making the full international preliminary examination for the purposes of the first written opinion (in general this is the WO of the ISA), the examiner should concentrate on trying to understand what contribution the invention as defined in the claims makes to the prior art. This should normally be sufficiently clear from the international application as filed. If it is not, the applicant should be invited to elucidate the matter (see paragraph III-4.2 [XR]); but the examiner should not raise an objection of this kind unless he is convinced it is necessary, since to do so might result in the applicant introducing additional subject matter going beyond the disclosure in the international application as filed (see paragraph VI-4.11 [XR]).

– *Inconsistencies Between Description and Claims*

Y.62 ~~42.67~~ [17] While any serious inconsistencies between the claims and description as filed should be objected to (see paragraphs III-4.3 [XR] and III-4.3a [XR]), it should be borne in mind that the claims may also require substantial amendment. In such a situation, the examiner might invite the applicant to amend the description to be in conformity with the final form of the amended claims even though the final form of the main claims may still not be settled. This procedure may help the examiner to expedite the issuance of the international preliminary examination report. However, it should also be appreciated that the applicant should not be put to unnecessary expense and trouble in providing an amended description if there is any likelihood that the claims will have to be changed again.

– *Recommending Amendments*

Y.63 ~~42.68~~ [E-VI-5.18] The examiner should not suggest amendments merely because he thinks they will improve the wording of the description or claims. A pedantic approach is

undesirable; what is important is that the meaning of the description and the claims should be clear. It must be emphasized that it is not part of the duty of the examiner to invite the applicant to amend the international application in a particular way to meet an objection, since the drafting of the application is the applicant's responsibility and he should be free to amend in any way he chooses provided that the amendment removes the deficiency and otherwise satisfies the requirements of the PCT. However, it may sometimes be useful if the examiner suggests, at least in general terms, an acceptable form of amendment; but if he does so, he should make it clear that the suggestion is merely for the assistance of the applicant and that other forms of amendment will be considered. The form of the amendment should be as prescribed in Rule 66.8(a).

[End of Annex II and of document]