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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:
EPO RESPONSE TO DOCUMENT PCT/MIA/7/2

Document prepared by the International Bureau

1. The comments appearing in Annex I of this document and the review of unity of invention practice at the European Patent Office (EPO) in Annex II were provided by the EPO.

2. *The Meeting of International Authorities is invited to consider the comments and information contained in this document.*

[Annex I follows]

ANNEXI

COMMENTS FROM THE EPO ON THE PROPOSED PCT GUIDELINES

[Regarding the numbering of the paragraphs this is based on the WIPO document with the original numbering from the USPTO suggestions sent to the EPO in brackets]

CHAPTER 2

- 2.05 Rule 23.1 should be mentioned here, since this deals with the transmittal of the search copy from the RO to the ISA,
- 2.10d Rule 16.3 should be mentioned here. Suggested change in wording (minor clarification): “to determine whether to use the result s..., and to consequently authorize...”
- 2.15b Rule 46.4 should be mentioned here.
- 2.16 Rule 44ter.1 should be mentioned here.
- 2.17 It should be made clear that if the applicant files amendments under Article 19 after a Written Opinion by the ISA but does not file a Demand for Chapter II, the International Preliminary Report on Patentability (by the ISA) will be established without taking these amendments into consideration (Rule 44bis).

CHAPTER 4

- 4.01, 4.52 In the second paragraph, the word “are encouraged to” should be replaced by “may” in the sentence “ISAs are encouraged...” since “encouraged” suggests that it is something that examiners should routinely do or at least impose a moral obligation.
- 4.14
(4.10) In line 6 delete “including databases listed in Annex B” since such an annex has not yet been agreed upon.
- 4.31, 4.40
(4.27, 4.36) Is now considered OK, brackets can be deleted.
- (4.41) Reference to databases and annexes to be deleted.
- 4.51 (4.47) In the third line change “should also endeavor to discover...” to “may, in appropriate circumstances, extend the search so as to discover”.
- 4.57 (4.53) We cannot agree to this paragraph since Rule 43.6 clearly states that it is optional to indicate the search history.

CHAPTER 6

6.19(AU -S-9.7) In these condline add after “mentioned” “ *on the request form*” to clarify where the applicant’s name is mentioned.

6.37(AU -S-4.1) The details given here of the amendment of the title and/or abstract by the ISA are incomplete. In particular the relationship between the Receiving Office and the ISA, and the communication between the two offices according to Rule 37 PCT (w.r.t. the title) and Rule 38 PCT (w.r.t. the abstract), in particular the cases where the RO has not informed the ISA that it has requested a title or abstract from the applicant when it is missing, which leads to the ISA preparing the title or abstract (Rule 37.2 and Rule 38.2(a) PCT). This should be differentiated from the situation where the RO has informed the ISA of the fact that it has requested the title and/or abstract from the applicant in accordance with Rule 26.1(b) PCT, but the ISA has not yet heard from the RO that these have been received or that the application is deemed withdrawn according to Art. 14(1)(b) PCT due to the applicant’s failure to file the title and/or abstract on time. This section could contain the advice to the examiner not to start the search where this is the case until it hears from the RO that the missing documents have been filed, since the examiner may perform search work on an application which is subsequently deemed withdrawn.

6.39(AU -S-4.2)(c): change the first sentence to read “ *only one figure should normally be selected. The...*”.

(d): second line, change “text” to “ *abstract*”.

6.46(AU -S-4.10) This wording could be replaced by wording taken from EPC Guidelines, which is more complete (EPC Guidelines, A -III 7.1 adapted to the PCT procedure):

“Title of the invention. According to Rule 4.3 PCT, the title must be short and precise (preferably from two to seven words in English or when translated into English). Furthermore, the title should clearly and concisely state the technical designation of the invention and should exclude all fancy names. In this regard the following should be taken into account.:

(a) personal or trade names, fancy names, the word “patent” or similar terms of a non-technical nature which do not serve to identify the invention should not be used;

(b) the abbreviation “etc.”, being vague, should not be used and should be replaced by an indication of what it is intended to cover;

(c) titles such as “Method”, “Apparatus”, “Chemical Compounds” alone or similar vague titles do not clearly state the technical designation of the invention.”

This section should also clarify that the ISA may change a deficient title at its own discretion according to Rule 37.2 PCT.

6.47(AU -S-4.11) See comments under S -4.1 above.

6.53–6.61

(AU-S-9.28-

AU-S-9.31) The EPO cannot go along with this level of detail with regard to the consulted documentation on the International search report, there is no legal obligation to provide this information in Rule 43.6 PCT. In any case it is already implicit that the ISA has consulted the minimum documentation since this is a requirement according to Rule 34 EPC and the EPO practice is to include IPC classes searched as far as the subclass level as required by Rule 43.6(a) PCT (e.g. C07J, A61K, C12N etc) and some general references are made to the databases consulted as provided for (but required by) Rule 43.6(c) PCT.

6.64

(AU-S-9.32)(a) add at the end “in particular where the validity of the claimed priority is in question”.

AU-S-9.32(b) The numbers of documents mentioned here are purely arbitrary, there should be no restrictions of the numbers of documents cited by the examiner other than the numbers should be reasonable in the context of the claimed invention.

AU-S-9.32(c) This statement could be clarified - it might be indicated here that where the same embodiments solving the same technical problem are disclosed in more than one document in the state of the art, then the examiners should attempt to reduce the number of documents cited by eliminating any redundancy in the technical content of the cited documents .

AU-S-9.32(d) See comments to AU -S-9.32(b). Additionally the Guidelines should avoid using frivolous terms such as “magical”.

AU-S-9.32(e) This section is absolutely unacceptable to the EPO, the examiner must have a completely free choice regarding the citation of abstracts or the source document, in particular since the sourced document may be in a language the examiner cannot reasonably be expected to understand (e.g. Japanese is not widely spoken in the EPO, US, AU, SE, ES, AT, CA offices and consequently the PAJ abstracts of Japanese patents are often cited instead of the parent document, where no family members are available in a more accessible language). Furthermore, where the abstract itself discloses the entire relevant content of the sourced document, then there is no need to cite the sourced document (for example citation of Chemical Abstracts with attached chemical compound records from CAPLUS database, means that there is no need to cite the sourced document in order to demonstrate the presence of relevant compounds in that document).

AU-S-9.32(e) Thereference hereto “foreign language” is not appropriate.

AU-S-9.32(f) For the purposes of assessing novelty and inventive step in preliminary examination according to Art. 35(2) PCT, it does not matter whether the prior art document was a patent document or a non-patent document. Consequently, there is no legal prerogative for the statement there (that preference should be given to the citation of patent documents). This preference does apply where the documents in question are overlapping patent rights published too late to be cited

according to Rule 33.1(a) PCT, but with a relevant date (filing or valid priority date) earlier than that of the application. The citation in the search report of such documents is provided for in Rule 33.1(c) PCT and their mention in the preliminary examination report is provided for in Rule 70.10 PCT. Such documents may give rise to objections according to national or regional legislation (for example Art. 54(3)(4) EPC). This should be clarified in this section.

6.67–6.93

(AU-S-8.32, 6.13-6.36)

These sections contain a lot of information relating to the assessment of the novelty and inventive step of the claimed invention. This section however, relates primarily to the claim categories on the International search report and is not primarily concerned with matters relating to novelty and inventive step. These matters are more appropriately dealt with in the sections relating to preliminary examination of novelty and inventive step. It is proposed to limit these sections purely to matters relating to the search report, the following wording is proposed as a replacement for these sections: -

“Categories of documents

All documents cited in the search report are identified by placing a particular letter in the first column of the citations sheets. Where needed, combinations of different categories are possible.

(i) Particularly relevant documents

Where a document cited in the International search report is particularly relevant, it should be indicated by the letters “X” or “Y”. Category “X” is applicable where a document is such that when taken alone, a claimed invention cannot be considered novel or cannot be considered to involve an inventive step.

Category “Y” is applicable where a document is such that a claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other documents of the same category, such combination being obvious to a person skilled in the art.

(ii) Documents defining the state of the art not prejudicing novelty or inventive step

Where a document cited in the International search report represents state of the art not prejudicial to the novelty or inventive step of the claimed invention, it should be indicated by the letter “A” (however, III, the opinions of the ISA are not binding on the IPEA, which may consider this document to be relevant in a finding of a lack of novelty or a lack of inventive step of the claimed invention).

(iii) Documents which refer to an unwritten disclosure

Where a document cited in the International search report refers to a non-written disclosure, the letter "O" should be entered. Examples of such disclosures include conference proceedings. The document category "O" is always accompanied by a symbol indicating the relevance of the document according to (i) or (ii) - e.g. O, X, O, Y or O, A.

(iv) *Intermediated documents*

Documents published on dates falling between the date of filing of the application being examined and the date of priority claimed, or the earliest priority if there is more than one (see Art. 2(xi)(b) PCT), should be denoted by the letter "P". The letter "P" should also be given to a document published on the very day of the earliest date of priority of the patent application under consideration. The document category "P" is always accompanied by a symbol indicating the relevance of the document according to (i) or (ii) - e.g. P, X, P, Y or P, A.

(v) *Documents relating to the theory or principle underlying the invention*

Where any document cited in the search report is a document which may be useful for a better understanding of the principle or theory underlying the invention, or is cited to show that the reasoning or the facts underlying the invention are incorrect, it should be indicated by the letter "T".

(vi) *Potentially conflicting patent documents*

Any patent document bearing a filing or priority date earlier than the filing date of the application searched (not the priority date) but published later than that date and the content of which would constitute prior art relevant to novelty (Art. 33(2) PCT) should be indicated by the letter "E" (see section 507(b) and Rule 33.1(c) PCT). Where the patent document and the application searched have the same date, the patent documents should also be identified by the letter "E". An exception is made for patent documents based on the priority under consideration.

(vii) *Documents cited in the application*

When the search report cites documents already mentioned in the description of the patent application for which the search is carried out, such documents may be identified on the search report by the wording "cited in the application", which appears under the cited document.

(viii) *Documents cited for other reasons*

Where in the search report any document is cited for reasons other than those referred to in the foregoing paragraphs (in particular as evidence), for example:

- (a) a document which may throw doubt on a priority claim (Art. 4(C)(4) Paris Convention)

(b) a document cited to establish the publication date of another citation,

such documents should be indicated by the letter "L". Brief reasons for citing the documents should be given. Documents of this type need not be referred to any particular claims. However, where the evidence which the provider relates only to certain claims (for example the "L" document cited in the search report may invalidate the priority in respect of certain claims and not others), then the documents should be referred to those claims.

(ix) Non-prejudicial disclosures

In certain cases the invention may have been disclosed in such a way that it is excluded from consideration as state of the art in accordance with the national law of one or more designated offices (this includes regional treaties, such as the EPC, governing intergovernmental organisations such as the EPO - Art. 2(x) PCT). The applicant may make a declaration of the existence of such excluded state of the art in the Request form according to Rule 4.17(v) PCT. However these exemptions do not necessarily apply in all designated contracting states and additionally according to Rule 51bis.1(a)(v) PCT, the applicant may still have to file the correct documents in the national/regional phase at the designated office in question in order to qualify for the exemption. Consequently such documents must be cited on the search report with the appropriate category indicated above and may also be considered in preliminary examination.

Relationship between documents and claims

Each citation should be referred to the claim to which it relates. If necessary, various relevant parts of the document cited should each be related to the claims in like manner (with the exception of "L" documents, see above). It is also possible for the same document to represent a different category with respect to different claims. For example:

X	WO9001867A (WIDEGREN LARS (SE))	1
	8 March 1990 (1990-03-08)	
Y	*figure 1*	2-5
A	*figure 2*	6-10

The above example means that Figures 1 and 2 of the cited document disclose subject matter which prejudices the novelty or inventive step of claim 1, which prejudices the inventive step of claims 2-5 when combined with another document cited in the search report, and represents non-prejudicial state of the art for the subject matter of claims 6-10.

Furthermore, each independent claim should be mentioned on the search report at least once in relation to at least one document published before the earliest priority date (unless the independent claim in question is excluded from the search by virtue of a restriction of the subject of the search mentioned in accordance with Art. 17(2) PCT or Art. 17(3) PCT."

6.101(AU -S-9.11) Here it is proposed that where the ISA bases its search results on an earlier search report prepared by the same ISA (Rule 16.3, PCT or Rule 41 PCT), that where the later search report differs from the earlier one on which it is based, the ISA should send a communication to the applicant explaining those differences (e.g. broader claims or intervening prior art found in a top-up search etc). This is not a requirement of the PCT and in any case, the ISA -WO can explain any contentious points in this regard.

6.85(6.30.5) The Guidelines is not the appropriate place to define new types of document symbols.

6.109–6.114(AU -S-10.1 to 10.6)
In our view there is no specific provision for this in the PCT, but it is rather a matter for each authority to decide upon (EPO for example does this as a service to the applicants). Further, since there is anyway a suggestion to reform R.91 from the IB under preparation, it is premature to insert such instructions into the Guidelines.

CHAPTER 9

9.02 Line 12: the wording “in conformance” is not clear.

9.12 Line 4: same as under 9.02

9.20 Line 2: “(preferably by facsimile transmission)” should be deleted.

9.58(9.60) Line 6: change “the file will not be forwarded to the examiner” to “*examination will not start*” since whether or not to forward a file should be left to internal practice.

CHAPTER 10

10.03 Technical character is not insisted upon.

10.08 In line 4 after “search report” add “*and the written opinion established under Rule 43bis(1)*” .

10.11(10.10) Change the last sentence to “*If the application complies with PCT Article 34(2)(c) the authority need not issue a written opinion but may establish the international preliminary examination report directly*”.

10.12(10.11) Line 2: change “should” to “would normally”. In line 7 add “should” before “study”.

(10.12) This paragraph is not clear and if clarified would be redundant with 10.13 and should therefore be deleted.

(10.13) In the first line amend “need not be required” to “is not required”.

(10.14) The second sentence (starting with However...) should be deleted since it gives the impression that provided the applicant has made a credible attempt to

overcome the objections, a second opinion should be issued (which is also in contradiction to 10.13)

(10.20) The procedure as to lack of unity should rather be dealt with in Chapter 12.

(10.20) Cancel “issuing a second written opinion” in line 10, since this sentence otherwise does not fit with the last line.

10.23(10.22) Inline 4 add after “(Rule 66.5),” “*the examiners should normally*”. Cancel the last sentence in brackets, since a detailed rebuttal does not appear appropriate. As stated in the previous sentence the applicant’s arguments will be taken into account.

(10.23) In the first line cancel “further” since this relates also to the first written opinion. Change “the file is to be forwarded to the examiner...” to “*the examiners should proceed to establish*” (it may not always be possible to give the file to the same examiner).

10.26(10.24) Should be deleted since it appears to relate to internal practice only.

(10.25) The wording “there is no restriction on resuming...” should be changed to “*International preliminary examination may exceptionally be resumed after a report...*” to clarify that this is rather an exceptional case.

10.39(10.34) We do not agree to the replacement sheets not being attached to the IPER since this is indeed a requirement of Rule 70.2.

10.40(10.35) Is considered acceptable, the text in brackets can be removed.

10.42(10.37) Inline 7 cancel “or the persons skilled... the mounting in question” to make the example correct.

10.49(10.44) Inline 6 change “it is not foreseen that” to “*it is not expected that*”.

10.51(10.46) We propose some general guidelines on interviews (personal or over telephone) to be inserted instead of the last two sentences (starting with “Communication...”):

(a) *When arranging an interview, whether personal or in the form of a telephoned discussion, the examiner will have to consider (i) the stage of procedure as well as (ii) the time left before the IPR phase is to be prepared.*

(i) *-If the WO -ISA is considered as the first written opinion by the IPEA under Chapter II, it is normally considered appropriate to grant a request for an interview made already with the response to this WO, unless the examiner has decided to send a further WO.*

-In case the WO -ISA is not considered as the first WO -IPEA then, on the other hand, an interview would normally not be granted until after a reply has been filed to the first WO -IPEA.

-In the case of lack of unity raised in the Search Report it would not appear appropriate to grant an Interview before a response to the invitation to restrict the claims or pay additional fees (Form 405) has been submitted.

(ii) -For a personal interview to be arranged there should be at least 2 months left until the IPRP has to be established in order to provide for proper arrangement, preparation and sufficient time after the interview for the applicant to file amendments as well as for the examiner to prepare the IPRP.

-If there is not enough time for a personal interview the examiner would normally call the applicant to inform him about this. If the issues are suitable for a telephoned discussion then maybe such an interview can be made over phone at that time. However, the limit date for the establishment of the IPRP must be carefully observed when setting the time limit for the applicant to file amended claims as a result of the conversation.

-Should the applicant insist on having a personal interview although the examiner judges that there would then not be enough time for establishing the IPRP before the 28 months, the applicant must give his approval to the IPRP being established after the 28 months as a consequence of the late interview.

(b) When an interview is arranged, whether by telephone or in writing, and whether by examiner or applicant, 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, on the file, the matters to be discussed as well as the date, time and location for the interview.

When a telephoned discussion (rather than a personal interview) has been chosen, the normal procedure would be for the examiner to telephone the applicant and request the applicant to phone back at a specific time. The examiner should record the particulars and briefly indicate, on the file, the matters to be discussed as well as the date and time for the applicant to call back.

In both cases a copy of the arrangements recorded should be sent to the applicant.

(c) If the applicant wishes to discuss amended claims during an interview (whether personal or over telephone) 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.

(d) The result of the personal interview or telephone conversations should be 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.

CHAPTER 12

- 12.02 Add reference to R.43bis.1(a)(ii). The amendment “which may be in the application” should be changed to “insofar as checked by the authority (Rule 66.2a(v)).
- 12.04 This section should clarify which time limit is applicable for applicants to reply, A.19(1)/R.46/R.66 and R.43bis. This is important since the time in question can vary depending on which provision applies.
- 12.13(12.12) Delete in line 2 the word “almost” since the WO of the ISA is always established on the basis of the application as filed. We feel that this paragraph is confusing since it does not clearly distinguish between the WO -ISA and WO -IPEA; amendments can only be taken into account at the IPE stage (concerns also 12.14).
- 12.22(12.21) In the first line after “sequence listings” change to *“one or more of the following indications must be given with respect to these sequence listings on which the examination is based: (i)....”*
- 12.30(12.29) This section should refer to the ISA as well.
- 12.48(12.47) In line 2 change “should” to “may” since Rule 43bis1 states that these requirements are indicated “insofar as checked by the ISA”.
- 12.49(12.48) In line 3 change “should” to “may” (see 12.48 and R.70.12(ii))
- 12.54 In line 2 change “should” to “must” (see Rule 43bis1).
- 12.57,58 Some confusion about ISA and IPEA procedures. See separate note.
- 12.63 It is not clear what is meant with an “improper” amendment.

CHAPTER 13

- 13.05 Delete last sentence since it does not seem to be connected to the previously stated.
- 13.13(13.12) We cannot agree to this paragraph since the emphasis has now changed from allowing claims of different categories in one application into allowing multiple claims of same category, but only different wording, in one application.
- 13.14(13.13) Regarding the options in brackets we would prefer the second option “However...”
- 13.20(13.19) We cannot agree to this wording which is clearly in contradiction with our interpretation of clarity. The middle paragraph starting with “Where the description...” until the end of the first bracketed paragraph “...taken into account” should be deleted and the original wording of E -III-4.2 reinstated (corresponds to the suggestion within the last brackets).

- 13.22(13.21) We cannot agree to the present wording, it is unclear to us what is the intended meaning. It seems to contain both unclear expressions “as if in the balance” and contradictory statements as to the limiting effect of the preamble.
- 13.26(13.27) We would agree to this paragraph with the text in brackets inserted. The last bracketed sentence, although it is acknowledged that it has been taken from our Guidelines, is not desired since our case law is changing in this respect and therefore the Guidelines will shortly be modified.
- 13.28(13.29) Add “and apparatus” since this is valid for both products and apparatuses appearing in a process claim.
- 13.32(13.33) We do not agree to the present wording, in particular the definition and determination of “scope” of invention does not appear appropriate (might be changed to “subject-matter”, but we think further discussions on this section are necessary).
- 13.34(13.35) We think that the wording “It is preferable not to use...” is not strict enough.
- 13.35(13.36) It is proposed to amend the Guideline on result to be achieved to include an objection under lack of support. This is in line with the rest of the Guideline which prescribes that no objections should be raised if there is compliance with support Guideline 13.43.

It is proposed to amend the paragraph on parameters to reflect the clarity issues as well, by incorporating text from EPC GLC -III, 4.7a. The word ‘meaningful’ has not been copied, but ‘useful’ was used, which is less controversial and in line with USPTO views on situations under proposed PCT Guideline 20.11.

Proposed text:

The area defined by the claims must be as precise as the invention allows. As a general rule, claims which attempt to define the invention, or a feature thereof, by a result to be achieved should be objected to as lacking clarity. Objection may also be raised under lack of support, because the claimed scope is broader than what the description enables. However, no objection should be raised if the invention can only be defined in such terms and if the result is one which can be achieved without undue experimentation (see paragraph 13.43)[xr], e.g., directly and positively verified by tests or procedures adequately specified in the description and involving nothing more than trial and error. For example, the invention may relate to an ashtray in which a mouldering cigarette end will be automatically extinguished due to the shape and relative dimensions of the ashtray. The latter may vary considerably in a manner difficult to define whilst still providing the desired effect. So long as the claim specifies the construction and shape of the ashtray as clearly as possible, it may define the relative dimensions by reference to the result to be achieved, provided that the specification includes adequate directions to enable the reader to determine the required dimensions by routine test procedures.

Where the invention relates to a chemical compound, it may be characterized in a claim in various ways, viz., by its chemical formula, as a product of a process or by its parameters. ~~Characterization of a chemical compound solely by its parameters may be appropriate in those cases where the invention cannot be adequately defined in any other way~~ provided that those parameters can be clearly and reliably determined either by indications in the description or by objective procedures which are usual in the art. The same applies to a process-related feature which is defined by parameters. This can arise, for example, in the case of macromolecular chains. But in such cases, only parameters usual in the art should be employed to characterize the compound. Cases in which unusual parameters are employed or an non-accessible apparatus for measuring the parameter(s) is used are prima facie objectionable on grounds of lack of clarity, as no useful comparison with the prior art can be made. The examiners should be aware of the possibility that applicants may attempt to employ unusual parameters to disguise lack of novelty (see paragraph 15.06[XR]).

The second paragraph relating to parameters should be merged with 13.57.

13.41 In the bracketed paragraph it is suggested to insert after “or language” *“where this has been originally disclosed”*. Further, it should be clarified if the term “negative limitation” has the same meaning to different authorities.

13.42 It is proposed to amend this section to reflect one of the central problems facing patent authorities: too many claims. Result-oriented tests from the EPC Guidelines are introduced.

Rule 6.1(a)

[E III-5.1] Therequirement that the claims shall be concise refer to the claims in their entirety as well as to the individual claims. For example, undue repetition of words or a multiplicity of claims of a trivial nature which render it unduly burdensome to determine the matter for which protection is sought, could be considered as not complying with this requirement. The number of claims must be considered in relation to the nature of the invention the applicant seeks to protect. What is or what is not a reasonable number of claims depends on the facts and circumstances of each particular case. Regard also has to be had to the interests of the relevant public. The presentation of the claims should not make it unduly burdensome to determine the matter for which protection is sought. Furthermore, the number of alternatives presented within a single claim should not make it unduly burdensome to determine the subject matter for which protection is sought.

13.44, 13.45 The word “description” should rather be “disclosure” in the title and in 13.45 lines 1 and 3.

13.48 In the first line cancel “The nature of the claimed invention” since this is not an appropriate expression.

13.51 In the title please delete “in Scope”. The original E III-6.2 should be reinstated.

13.57 We cannot agree to the present wording and would prefer the wording from our own Guidelines EPCC -III 4.7a, which gives the examiner the possibility of putting the onus of proof on the applicant if doubts arise.

13.58 Add at the end “(see paragraph 19.12)”.

13.61,62 Comments:

1. Chapter 13 is headed “Claims”; the inclusion of these paragraphs in this chapter is thus inappropriate.

2. The term “biologically reproducible” is not used in the PCT. We therefore suggest inclusion of a definition of “biological material” (which is used in Rule 13bis), taken from Rule 23b(3) EPC, i.e.:

“The term “biological material” means any material containing genetic information and capable of reproducing itself or of being reproduced in a biological system.”

3. The text also includes a “support” requirement in connection with deposits. This does not reflect the legal position in the EPC where, according to Rule 28 EPC, deposits are made in order to remedy sufficiency problems. Moreover, the disclosure in the application of relevant information on the characteristics of the deposited biological can be required only to the extent that it is “available to the applicant” (Rule 28(1)(b) EPC).

Proposed Revised Text

13.61 The term “biological material” means any material containing genetic information and capable of reproducing itself or of being reproduced in a biological system. Where the application refers to biologically reproducible material which cannot otherwise be adequately described in the application to meet the ~~enablement~~ sufficiency of disclosure ~~and support~~ requirements of Article 5 and 6, those requirements shall be considered to be complied with by a deposit of such material — the deposit of such material shall be taken into consideration when determining whether those requirements have been met.

13.62 The deposit shall be considered part of the description to the extent that the requirements regarding sufficiency of ~~description~~ disclosure under Article 5 ~~and the support requirement of Article 6~~ cannot otherwise be complied with so that it would be taken into account in determining the compliance with such requirements. Therefore, mere reference to the deposited material in an application ~~cannot simply~~ may not be sufficient to replace the disclosure of such material in the application in order to comply with those requirements. It should be noted, however, that a reference to the deposit in the application would not create the presumption that the deposit is necessary or required to comply with those requirements.

CHAPTER 14

- 14.05 Regarding the paragraph in brackets: our practice is to regard the priority as valid for the purpose of the WO in the case it cannot be verified.
- 14.10(14.08) We do prefer the first alternative. A suggestion would be to allow both procedures, i.e. to state the wording in brackets as an alternative way. This can simply be done by changing the word “Alternative” to “Alternatively”. However, it should be noted that it is not possible to define a new specific category symbol only in the Guidelines (see also 6.85).
- 14.13(14.10) This paragraph needs further discussion. Our practice in this field is at the moment different, but it would be interesting to hear the experiences of other authorities with Internet publications.

CHAPTER 15

- 15.01 We agree to the present definition of “explicitly or inherently” as stated within brackets. However, in line 8 the wording “persons of ordinary skill” should be replaced by “persons skilled in the art”.
- 15.03 Under (iii) add “in combination” after “disclosed”.
- 15.10 We agree to this paragraph.

CHAPTER 16

- 16.03 We cannot agree to this paragraph as it stands and would suggest the following amendments to be able to continue our practice on inventive step: change (ii) to “*the references must be considered as a whole and must prompt the skilled person into combining the documents so as to arrive at the subject-matter as claimed*”; and delete No (iv) (the reference to EPC Guidelines 9.9 here is not adequate since that paragraph talks about commercial success not normally being a criteria for inventive step).
- 16.07(16.06) Delete the last two sentences starting from “Also...” since the emphasis on enablement is more a question of novelty than of inventive step in our practice.
- 16.08(16.07) It is suggested to change this paragraph as follows in order to accommodate also the problem -solution approach. In the first paragraph it is proposed to make the following changes: In the first line change “methodology” to “*considerations*” and “used for” to “*applied for*”. In these second and third lines change the word “scope” to “*elements*”. The last line of the first paragraph should be cancelled. It is proposed to shift the third paragraph before the second. Moreover, in the present third paragraph there is a drafting problem in the wording “the person skilled in the art would have motivated the person of skill in the art...”.
Further, to give a clear review on the problem -solution approach it is suggested to add the following paragraph instead of the present second paragraph in brackets (based on the USPTO suggestion with text added (partly modified) from the EPC Guidelines C- IV 9.4). Please note that the requirement of technical progress is not

are requirement for the problem -solution approach (as explicitly indicated in the paragraphs below). Nevertheless, according to the problem -solution approach an objective problem can always be formulated (“finding an alternative”, “making it easier to manufacture”, “cheaper to manufacture”) even in the case where there is no technical progress.

Proposed text:

“One specific method of assessing inventive step might be to apply the so called problem -solution approach. The approach consists of the following stages:

- 1. determining the closest prior art (see also I 6.08);*
- 2. establishing the objective technical problem to be solved; and*
- 3. 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.*

Step 1

The closest prior art is that combination of features derivable from one single reference that provides the best basis for considering the question of obviousness. The closest prior art may be, for example:

(i) a known combination in the technical field concerned that discloses technical effects, purpose or intended use, most similar to the claimed invention or

(ii) that combination which has the greatest number of technical features in common with the invention and is capable of performing the function of the invention.

Step 2

In the second stage one establishes in an objective way the technical problem to be solved. To do this, one studies the application (or the patent), the closest prior art, and the difference in terms of features (structural and functional) between the invention and the closest prior art, and then formulates the technical problem.

In this context the technical problem means the aim and task of modifying or adapting the closest prior art to provide the technical effects that the invention provides over the closest prior art.

The technical problem derived in this way may not be what the application presents as “the problem”, 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.

The expression technical problem should be interpreted broadly; it does not necessarily imply that the solution is a technical improvement over the prior

art. Thus the problem could be simply to seek an alternative to a known device or process providing the same or similar effects or which is more cost-effective.

Sometimes the features of a claim provide more than one technical effect, so one can speak of the technical problem as having more than one part or aspect, each corresponding to one of the technical effects. In such cases, each part or aspect generally has to be considered in turn.

Step 3

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) prompt the skilled person, faced with the technical problem, to modify or adapt the closest prior art while taking account of that teaching, thus arriving at something falling within the terms of the claims, and thus achieving what the invention achieves."

16.13(16.10) Under (ii) change this sentence to "whether the documents are reasonably pertinent to the problem underlying the invention" since it is not relevant whether the documents are pertinent to the particular problem with which the inventor was concerned. (This might lead to the applicant formulating a very strange problem not related to any normal prior art.) The only criteria should be whether the skilled person would (for some reason - see under 16.07 regarding problem -solution approach) combine the two documents or not. Starting from the closest prior art the problem which the inventor thought they had solved might be totally irrelevant, since this item of prior art might very well show that what the inventor started from is actually not the closest prior art. Thus, it doesn't matter why the skilled person would have combined the documents or whether they mention the problems solved by the inventors as long as a combination can be shown to have been obvious and lead to a device (or method, etc) having all the features of the discussed claim. See also last four lines of 16.11.

16.15(16.12) In Example (b)(ii) add at the end "providing the means for overcoming the technical difficulties are defined in the claim".

CHAPTER 17

Needs further discussion, cannot be accepted as it stands.

CHAPTER 19

19.14(19.12) Suggested change:

19.14 [E II-4.10] It is the responsibility of the applicant to ensure that he supplies, when he first files his international application, a sufficient disclosure, that is, one that meets the requirements of Article 5 in respect of the invention, as claimed in all of the claims (see paragraphs 13.43 -13.53 [XR]). If the disclosure is seriously insufficient, such a deficiency cannot be cured subsequently by adding further examples or features without offending against Article 34(2)(b) which requires that the subject matter content of the application must not go beyond the disclosure in the

international application (see paragraphs 11.02[XR] and 10.34[XR]). Where the disclosure is insufficient to enable a person skilled in the art to carry out the claimed invention, the claim may also be too broad to be supported by the description and drawings. Therefore, in that case, there may be non-compliance with both the requirement concerning sufficiency under this paragraph and the requirement of support of the claims (see paragraphs 13.54 - 13.58).

CHAPTER 20

20.02-20.06 As regard the provisions relating to excluded matter in these sections the EPO reserves its position pending conclusion of ongoing discussions within the office. Suffice it to say that it does have serious reservations concerning some of these provisions, particularly insofar as they relate to computer programs and business methods.

20.01, 08, 10, 11

[Note: 20.01 is modified merely for clarification. The present version refers only to 'no search at all' to 20.10 - 20.16, but this is incorrect because 20.10 etc also deal with situations where search is carried out. GL's 20.10 and 20.11 are clarified, and amended to cover more situations. 20.08 is modified to reflect the agreed reading of Article 17(2)(b). The heading "Exceptional Situation" of 20.10 does not match the content of 20.10 because that Guideline also deals with situations where search is carried out.]

Proposed amended paragraphs:

20.01 The aim of the Authority should be to issue international search reports and international preliminary reports on patentability that are as complete as possible. Nevertheless there are certain situations in which no search is issued, or in which the search, written opinion or international preliminary examination report covers only a part of the subject matter that a report would usually cover. This may be either because the international application includes subject matter which the Authority is not required to deal with (see paragraphs 20.02 - 20.09 [XR] below), 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 paragraphs 20.10 - 20.20 [XR] below). The term "meaningful search" in Article 17(2)(a)(ii) should be read to include a search that within reason is complete enough to determine whether the claimed invention complies with the substantive requirements, i.e., the novelty, inventive step, and industrial applicability requirements, and/or the sufficiency, support and clarity requirements of Articles 5 and 6.

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 a part or parts of the application are not in compliance with the prescribed requirements, a search should be performed even if for the purposes of determining the scope of a meaningful search, then non-compliance is

taken into account. See paragraphs 20.10 - 20.16 for further discussion and examples on this issue.

[...]

Excluded Matter in Only Some Claims ~~or Parts of Claims~~

Article 17(2)(b)

20.08 Where the subject matter of only some of the claims ~~or part of a claim~~ is a subject excluded from the search, this will be indicated in the international search report and written opinion. Search should of course be made in respect of the other claims or other parts of a claim.

[...]

“Exceptional Situations” – Scope of the search in certain situations

20.10 There may be exceptional situations where the description, the claims or the drawings fail to comply with the prescribed requirements to such an extent that a meaningful search cannot be carried out, i.e., no search at all is possible for a particular claim (see 20.01 [XR]). ~~To the extent that~~ However, in certain [complex] situations where the description, the claims, or the drawings can be sufficiently understood, even though a part or parts of the application are not in compliance with the prescribed requirements, a search should be performed even if for the purposes of determining the scope of a meaningful search, the non-compliance is taken into account. a search in the probable areas relevant to the claimed subject matters should be performed. The written opinions should ~~also~~ then indicate, however, how the description, claims, or drawings fail to comply with the prescribed requirements. In this indication, it may should also be noted by the ISA to what extent that non-compliance with the particular prescribed requirements has been taken into account for the purposes of determining the scope of the search, and this scope should be indicated as precisely as possible.

20.11 Examples

I. Examples Where Search or Preliminary Examination is Possible, with an Indication in the Written Opinion (see 20.10 [XR])

20.11 Examples

Example 1

Claim 1. Distillate fuel oil boiling in the range 120 °C to 500 °C which has a wax content of at least 0.3 weight% at a temperature of 10 °C below the Wax Appearance Temperature, the wax crystals at that temperature having an average particle size less than 4000 nanometers.

The description does not disclose any other method of obtaining the desired crystals size than the addition of certain additives to the fuel oil and there is no common general knowledge of making a fuel oil of this kind available to the persons skilled in the art.

A search would first be made for the additive and fuel oil having defined amounts of the additive disclosed. The field of search would then be extended to all probable areas relevant to the claimed subject matter, i.e., the broad concept of fuel oil compositions having the desired property. However, the search need not be extended to areas in which it could reasonably have been determined that there was a low probability of finding the best reference. If the broad concept of having crystals as small as possible was known in the art, the written opinion should indicate the claim as either not complying with the requirements of novelty and/or inventive step. The written opinion should also include any observations on non-prior art grounds. In this example, the claim would be objected to in the written opinion on the following non-prior art grounds: (1) it is not supported by the description and drawings "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art" (paragraph 13.44 [XR]); and (2) it is not fully supported in the description and drawings thereby showing that the applicant only claims subject matter which he recognized and described on the filing date (paragraph 13.54 [XR] and paragraph 13.58 [XR]). The International Search Report would cite the fields of search, the most relevant references for prior art purposes, and where possible, the most relevant references for non-prior art "T" should be used for designating documents which are of assistance in determining lack of industrial applicability and lack of support by the description), 6.06 (directed to the category symbol to be used for subject matter which may be excluded from the international search) [XR]), which in this example involve a lack of support by the description. The ISA may should also include in the objection on non-prior art grounds an indication to what extent ~~that~~ these objections have been taken into account for purposes of determining the scope of the search, and this scope should be indicated as precisely as possible, e.g. the additive and fuel oil having defined amounts of the additive disclosed and/or the broad concept of fuel oil compositions having the desired property.

Example 2

Claim 1: "A process of reacting starting materials in such a way that a sustained release tablet with improved properties is obtained."

The specification discloses an example of reacting particular materials in a particular manner to obtain a sustained release tablet having a particular release rate of a particular bioactive material. (This is an example of a claim which is defined solely by the result to be achieved.)

A search would first be made for the particular materials reacted in the particular manner. If the particular example disclosed could not be found, the search would then be extended. For instance, the search could be extended to sustained release tablets having the particular bioactive material. However, the search does not need to be extended to areas in which it could reasonably have been determined that there was a low probability of finding the best reference. Aside from any opinion on novelty or inventive step, the written opinion should indicate any observations on non-prior art grounds. In this example, the claim would be objected to in the written opinion on the following non-prior art grounds: (1) the claim lacks clarity since (a) the claim fails to recite any positive, active steps such that the scope of the invention is not set forth with a reasonable degree of clarity and particularity (paragraph 13.33 [XR]), and (b) the phrase "improved

properties” is a relative term (paragraph 13.35 [XR]); and (2) the claim attempts to define the invention solely by the result to be achieved (paragraph 13.36 [XR]). Again, the International Search Report would cite the fields of search, the most relevant references for prior art purposes, and the most relevant references for non-prior art purposes. Also, the ISA ~~may~~ should also include in the objection on non-prior art grounds an indication to what extent ~~that~~ these objections have been taken into account for purposes of determining the scope of the search and this scope should be indicated as precisely as possible, e.g. the particular materials reacted in the particular manner.

Example 3

Claim 1: “A fat having a nouse index of less than or about 1.0.”

The specification discloses a number of fats that purportedly have a nouse index of less than 1.0 and a number of fats which have a nouse index greater than 1.0. Examples of fat having a nouse index of less than 1.0 included different mixtures of saturated and unsaturated fats. Examples of fat having a nouse index greater than 1.0 also included different mixtures of saturated and unsaturated fats. No other properties, e.g., melting point, of these mixtures of fats are disclosed. The specification discloses determining the nouse index by whipping the fat at a particular speed and temperature and measuring the viscosity of the whipped mixture at room temperature. (This is an example of a claim defined solely by unusual parameters.)

A search should first be made for the examples disclosed in the specification as having a nouse index less than or about 1.0. If one of these examples is found in the prior art, an opinion that the claim lacks novelty over the prior art would be made since the same material would be expected to have the same properties. The claim would also be objected to on the following non-prior art grounds: (1) the claimed subject matter is not supported by the description and drawings “in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art” over the entire scope of the claim (paragraph 13.44 [XR]); ~~and~~ (2) the claimed invention is not fully supported in the description and drawings thereby showing that the applicant only claims subject matter which he had recognized and described on the filing date (paragraph 13.54, 13.58 [XR]) and (3) the claimed invention lacks clarity because it is unduly burdensome to compare the claimed subject matter with the prior art. If one of these examples is not found, the search need not be limited to only the examples simply because a newly described/discovered parameter is used by applicant to explain the invention. A search can usually be performed using other known parameters or chemical or physical properties that may lead to a conclusion that the newly described/discovered parameter is necessarily present, i.e. inherent. For instance, in this example, perhaps a search using a parameter such as the extent of saturation could be made. Also, the ISA ~~may~~ should also include in the objection on non-prior art grounds an indication to what extent ~~that~~ these objections have been taken into account for purposes of determining the scope of the search and this scope should be indicated as precisely as possible, e.g. the examples disclosed in the specification and/or other known parameters or chemical or physical properties that imply the presence of the new parameter.

Example 4, Complex Markush -type claim

[asatisfactoryapproachtothesetypesofclaimshasnotyetbeendeveloped. One prongoftheapproach,however,mayinvolvebreakingtheclaimupintodifferent embodimentsunderlackofunity. Not newly added Example 23 bis in Chapter 21].

Example 5

An application contains 480 claims, of which 38 are independent. There is no clear distinction between the independent claims because of overlapping scope. There are so many claims, and they are drafted in such a way, that it is unduly burdensome to determine the matter for which protection is sought from the claims. However, there is a single reasonable basis in the description, for example from a particular passage, that clearly indicates which subject matter might be said to represent the heart of the invention

The search should be based on the subject matter representing the heart of the invention. The claims should be objected to on the non -prior art grounds of lack of conciseness and lack of clarity as a whole. The ISA should also include in the objection on non -prior art grounds an indication that these objections have been taken into account for purposes of determining the scope of the search, and this scope should be indicated as precise as possible, for example by a brief written description of the searched subject matter, where possible citing a particular passage.

II. Examples Where No Search At All Is Possible for All or Some of the Claims (see 20. 01 [XR])

Example 1

Claim 1: "My invention is worth a million dollars."

Claim 1 is the only claim in the application. The specification discloses a number of inventions which, if claimed, would lack unity of invention.

No search at all is possible for claim 1.

Example 2

Claim 1: "My invention is worth a million dollars."

There are other claims in the application, setting out clear technical details of the invention.

No search at all is possible for claim 1. The other claims are researched.

Example 23

Claim 1: A composition of matter comprising kryptonite.

The specification recites the term “kryptonite”. However, the specification fails to define the purported material in terms of any of the elements of the periodic table. The specification also fails to set forth any of the physical properties of the purported materials such as density, melting point, etc.

No search at all is possible for claim 1.

Example 4

An application contains 480 claims, of which 38 are independent. There is no clear distinction between the independent claims because of overlapping scope. There are so many claims, and they are drafted in such a way, that it is unduly burdensome to determine the matter for which protection is sought from the claims. There is no single reasonable basis in the description or elsewhere, for example from a particular passage, that clearly indicates which subject matter might be said to represent the heart of the invention.

No search at all is possible.

- 20.15 The middle paragraph of this section seems to mix ISA and IPEA issues and should be redrafted. Further, on line 17 the wording “and should ask” should be changed to “and may ask”, since this is at the examiners’ discretion.

CHAPTER 21

This chapter should be further discussed in detail with the Authorities. In order to provide a good basis for such a discussion we have annexed a detailed explanation on our practice with respect to Unity.

Regarding the examples in present Chapter 21 the following remark is made: with respect to the Biotec example on SNP’s, this is a point of discussion in a trilateral working group on SNP’s and haplotypes. Any decision on these examples should thus await the publication of the report of this group.

CHAPTER 22

In our opinion this chapter is premature until the suggestion from IB on a amended Rule 91 is taken into account.

[Annex II follows]

ANNEXII

UNITY OF INVENTION - CURRENT PRACTICE AT THE EPO

GENERAL PRINCIPLES AND CRITERIA CONCERNING UNITY OF INVENTION

Rule 13 deals with the requirement of unity of invention and states in R 13.1 the general principle that the application should relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. R 13.2 gives an interpretation of the concept of unity of invention where a group of inventions is claimed.

Unity of inventions serves a regulatory function

The requirement of unity of inventions serves a regulatory function in the interest of an efficient procedure. It would be inappropriate to accept those applications which, because of their heterogeneous content, entail a far greater than average expense to process, especially in respect of search, since this expense must partly be borne by the fees levied for other applications. A further aspect is the requirement of a steady comprehensibility of the subject-matter of the application, which may be impaired by heterogeneous subject-matter.

On the other hand the general purpose of dealing with interconnected substantive issues within a single procedure would not be achieved, if provisions relating to unity of invention were applied too strictly. For this reason interconnected matters should not be split up needlessly.

Criteria for unity of invention

The requirement of unity of inventions should always be applied with a view to giving the applicant fair treatment, and additional fees should be charged only in clear cases.

A narrow, formalistic or academic approach should be avoided. However, in clear cases of lack of unity, an objection should be raised.

Single general inventive concept

The requirement of unity of invention referred to in R 13.1 is fulfilled only when there exists a single general inventive concept among the claimed separate inventions which finds its expression in one or more of the same or corresponding special technical features (R 13.2). It should be noted, however, that neither R 13.1 nor R 13.2 require that the concept linking the claimed separate inventions be expressly stated in the wording of the claims.

Actual content of the claims

It is not the formal choice of words or form of claims, but the actual content of the claims interpreted in the light of the description which establishes the technical relationship between the subject-matter of different claims, and which is thus decisive for the question of unity.

Categories

The mere fact that an application contains claims of different categories, or several independent claims of the same category, is in itself no reason for objection on grounds of lack of unity of invention.

Alternatives with a claim

It is also irrelevant whether the inventions are claimed in separate claims or as alternatives within a single claim (R13.3).

Sequence of the claims

Similarly in normal cases the sequence of the claims should not have an impact on the determination of unity of invention.

Different groups of the classification

The fact that the claimed separate inventions may belong to different groups of the classification is also not a reason in itself for a finding of lack of unity. As a matter of principle the determination of unity of inventions should not be based on the state or structure of the search documentation.

Assessing unity of invention

As far as the meaning of the single general inventive concept according to R13 is concerned it must be taken into account that, even if there are the same or corresponding features representing a single general concept among the claimed separate inventions, there is nevertheless lack of unity of invention if the concept is known. Therefore, when assessing unity of invention, the novelty of the single general concept has to be examined first of all. If novel, the inventive character of that concept has to be assessed. This does not mean that a comprehensive examination of inventive step has to be carried out when determining unity of invention. In cases of doubt the benefits should be given to the applicant.

Forming an opinion on whether or not there is unity of invention requires the determination of the technical problem(s) underlying the claimed separate inventions. This is an important step in the process of finding whether or not there exists a single general inventive concept. The determination of the problem(s) has to be based on the contents of the claims with due regard to the description and any drawings.

Any finding of lack of unity of invention must be based on sound reasons. Such reasons should comprise the relevant considerations relating to the number and the grouping of the claimed inventions, and also the arguments behind the finding of lack of unity.

R13 PCT provides for two legitimate approaches towards a logical reasoned statement regarding unity of invention (R13.1 and 13.2).

The focus of the first approach is on the requirement that there must exist a single general inventive concept. In this approach the technical features that are the same or corresponding in all these separate inventions are identified. These features are then used to describe a single general concept. If the single general concept is known from the prior art, then there is no

single general inventive concept and unity is lacking. If the single general concept is not known from the prior art, unity is present.

The focus of the second approach is on the identification of special technical features. The special technical feature(s) of the first invention is (are) compared with the special technical feature(s) of the second and further inventions. If these features are not the same or not corresponding unity is lacking.

Single General Inventive Concept Approach

Where there is a single general concept that appears to be novel and inventive, the application is considered to meet the requirement of unity.

There will be cases in which it is possible to draw sound conclusions on the question of unity of invention by applying the following approach.

Step 1: The examiners should identify the independent claims of the application.

Step 2: A single general concept should be formulated, i.e. a solution to a single problem based on an analysis of the technical features of the independent claims, and of its technical consequences which are expressed as effects.

Step 3: If no single general concept can be distinguished, or if the single general concept is clearly known from the state of the art at hand, then the application lacks unity of invention.

However, where an independent claim lacks novelty or inventive step, the above approach cannot be limited to this claim, but must be extended to include an analysis of those dependent claims which involve a contribution over the prior art.

The single problem as mentioned in Step 2 should be as narrow as possible whilst still covering all separate independent claims. The concept should be defined on the basis of the contents of the application.

Often the effects of the technical features and consequently the problem to be solved are not derivable from the independent claims, e.g. when dealing with compounds *per se*. In such cases the effects, activity or other properties disclosed by the application should be taken into account when formulating the problem to be solved.

In such cases of compounds *per se*, where the structure as a whole is often responsible for the specific properties or effects, whereas individual structural elements (such as side chains, substituents, etc.) taken in isolation cannot be associated with the properties or effects, the principles set out below (Particular situations: Alternative in a single claim) should be adhered to.

Special Technical Feature Approach

Within the meaning of R 13.2 the expression *special technical features* means those technical features which define a contribution which each of the inventions, considered as a whole, makes over the prior art. It should be noted that the special technical features cannot always be equated with the specific technical features recited explicitly in a claim or in a particular

combination of claims. Thus, in some cases a special technical feature may be linked with a property or a special technical effect not mentioned in the claims

For this reason a comparison of the features of claims which possibly lack unity of invention has to take into account the contents of the descriptions so that, with its help, the effects associated with the features of the claims can be established. Only on the basis of such examination can it be decided whether there are common or corresponding special technical features.

Analysis of unity of invention

The following approach to the analysis of unity of invention can be applied on the basis of R 13.2.

- Step 1: In a first step the claims are analysed in the light of the description and the drawings, if any, with a view to identifying in a *prima facie* manner all claimed separate inventions.
- Step 2: In a second step the relevant pieces of prior art are identified on the basis of an analysis of the entire state of the art available at that stage.
- Step 3: The third step consists in determining from the differences over the relevant prior art identified in step 2 the objective technical problem(s) underlying the claimed separate inventions.

In general it is most efficient to start with the same approach as the applicant as far as the determination of the technical problem(s) is concerned.

It is not unusual, however, that the technical problem(s) has (have) to be reformulated in view of documents found in the search. Similarly the technical problem(s) may have to be reformulated if it appears in view of the available evidence that the combination of technical features in the claims does not solve the initially stated technical problem(s) over the whole area covered by the claims.

- Step 4: In this step the solution(s) offered by the claimed separate inventions are analysed with a view to establishing:
- (i) the technical contribution which each of the claimed inventions makes over the prior art ;
- and
- (ii) the general idea(s) underlying the proposed solution(s), i.e. the basic thoughts and insights on how the given technical problem(s) can be solved.

On the basis of these considerations it will be possible to determine whether or not the claimed separate inventions are linked by a single general inventive concept. Equally it will be possible to identify the special technical feature(s) of each of the claimed inventions, i.e. those technical features which are in essence contributing to the solution of the technical problem(s) or, in other words, those technical features or combination of features which produce the desired results and effects.

- Step5: In step 5 a conclusion is drawn with regard to the presence or absence of unity of invention on the basis of the results of the previous steps.
- Step6: Subsequently, in the sixth step the claimed separate inventions are classified into groups, and the respective numbers of the claims or, if this is not possible, the subject-matter belonging to each particular group, is identified. As a matter of principle all inventions within a particular group should be regarded as meeting the requirement of unity.

Several independent claims in the same category

The requirement of unity has to be met by the subject-matter of the independent claims in the same category. Thus the single general inventive concept must be either implicitly or explicitly present in each of the independent claims.

Several independent claims in the same category directed to interrelated subject matter may meet the requirement of unity, even if it appears that the claimed subject-matter is quite different, provided that the special technical features making a contribution over the prior art are corresponding. Examples for such situations include a transmitter claimed together with a corresponding receiver, a plug claimed with a corresponding socket etc. Special attention is required in the situation of claims characterised by a combination of elements (eg A+B+C), accompanied by claims relating to sub-combinations (eg A+B, A+C, B+C or A, B, C separately). Even if the claimed sub-combinations define patentable subject-matter, and the combination claim includes all the features of the claimed sub-combinations, lack of unity of invention may arise.

Independent and dependent claims

Unity of invention has to be considered in the first place only in relation to the independent claims and not the dependent claims.

Lack of unity does not arise in respect of any claims that depend on an independent claim, as long as the independent claim has unity in itself and it does not appear to be anticipated by the prior art available to the examiner. For this reason examiners should not concern themselves with the unity of invention of dependent claims, provided they are satisfied that these claims are truly dependent, i.e. they include all the features of the independent claim to which they refer back.

This principle applies irrespective of whether or not the dependent claim contains subject-matter which could be made the subject of a further independent claim (R13.4).

In the case where a claim referring back to an independent claim is not a true dependent claim this claim should be regarded as an independent claim for the purpose of assessing unity of invention. This situation is illustrated, for example, by a claim referring to a claim of different category, or by a claim including alternative features which do not specify the features of the claim referred to, but are intended to substitute those features.

If the independent claim appears to be anticipated by the prior art available to the examiner, for example because of lack of novelty, then the question whether there is still a single general inventive concept between the dependent claims needs to be carefully considered. In this

particular situation the claims must be considered and analysed, in respect to each other, as if they were independent claims.

Particular situations

There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

- (i) combinations of different categories of claims;
- (ii) so-called Markush practice; and
- (iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2. Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

Rule 13.3 requires that the determination of the existence of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. Therefore lack of unity may arise in a single claim embracing several alternatives. Examiners should be aware that such a claim is equivalent to a set of claims defining each alternative separately.

Rule 13.3 is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in Rule 13.2) remains the same regardless of the form of claim used.

Rule 13.3 does not prevent an International Searching or Preliminary Examining Authority or an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fees system applicable in that Authority or Office.

Combinations of different categories of claims

The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,

it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words specially adapted are not intended to imply that the product could not also be manufactured by a different process. Also an apparatus or means shall be considered to be specifically designed for carrying out a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression specifically designed does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

The list is not exhaustive and other combinations may be permitted under certain conditions. Thus the novelty and inventive step of a given product might justify the presence of independent claims relating to several new uses of the product in different areas and/or several new processes for preparing the product.

It should be noted that the presence of expressions such as “specially adapted” or “specifically designed” does not imply automatically that a single general inventive concept is present if such phrase appears in a claim. In each case it has to be examined whether the requirements laid down in R 13 are met. The same or corresponding special technical feature(s) that render(s) a process or apparatus specially designed or adapted to a given product or process need to be present in the claim to the process or apparatus in order to fulfil the requirement of R 13.2.

Alternatives in a single claim

Markush Practice.

This situation involving the so-called “Markush practice” where in a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

- (i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
 - (A) all alternatives have a common property or activity, and
 - (B) a common structure is present, i.e., a significant structural element is shared by all of the alternatives.

In paragraph (i)(B) , above, the words significant structural element is shared by all of the alternatives refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure

constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

- (ii) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.
- (iii) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of inventions shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. The examiner will assess whether the teaching of the prior art document clearly shows that the Markush alternative from the prior art documents solves the same problem as the patent application does. Only in that case the Markush claim lacks unity of invention.

Intermediate and final products

This situation involving intermediate and final products is also governed by Rule 13.2.

- (i) The term "intermediate" is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.
- (ii) Unity of inventions shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:
 - (A) the intermediate and final products have the same essential structural element, in that:
 - 1) the basic chemical structures of the intermediate and the final products are the same, or
 - 2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and
 - (B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.
- (ii) Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there shall be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element into the final product.

- (iii) It is possible to accept in a single international application different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.
- (iv) The intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new.
- (v) If the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.
- (vi) If the intermediate and final products are families of compounds, each intermediate compound shall correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities shall not affect the decision on unity of invention.

The examiner is able to make a complete search

Occasionally the examiner is able to make a complete search for all claimed inventions with little additional work and cost, although a situation of lack of unity is found to exist. In such cases a complete search is made and all these search results are included in the complete international search report. Nevertheless the finding of lack of unity is indicated in the international search report and the (group of) inventions are identified but no further search fees are requested from the applicant.

Logically presented technical reasoning

When raising or confirming an objection of lack of unity, the substantive examiners should always set out logically presented technical reasoning containing the basic considerations behind the finding of lack of unity (R40.1). The reasons should also comprise the considerations relating to the number and the grouping of the claimed separate inventions. Sufficient details should be given.

Partial search; at least first invention

If the examiner finds that the international application does not meet the requirement of unity of invention, he carries out a partial search which covers at least the first invention, i.e. normally the invention or group of inventions first mentioned in the claims ("main invention") A17(3)(a).

Reasoned statement; where appropriate a warning

The examiner identifies each of the different inventions or groups of inventions covered by the claims and draws up a reasoned statement explaining the grounds for finding a lack of unity between them (R40.1). *Where appropriate* (i.e. only in those cases where the examiner suspects that one or more of the as yet unsearched inventions might subsequently be found to

lack of unity), the reasoned statement (on Form PCT/ISA/206) shall inform the applicant that the grouping of the claimed inventions has been made on the basis of a partial search result and include a warning, worded as follows, which is added at the end of the reasoning

“The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched group(s) of invention(s), then the further search(es) may reveal further prior art that gives evidence of a further lack of unity “a posteriori” within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search. No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims (“main invention”) and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the Administrative Instructions under the PCT or the International Search and Examination Guidelines provide a legal basis for further invitation to pay further additional search fees”

SUBSEQUENT FINDINGS OF LACK OF UNITY IN PCT CHAPTER I

Exceptional case

In order to avoid issuing more than one invitation to pay additional fees the procedure described below is to be followed.

In all cases it is essential that there is a clear, subsequent, lack of unity which is to be communicated on Form PCT/ISA/210, i.e. the International Search Report. If there is any reasonable doubt the search must be completed.

The procedure

The procedure is as follows

The ISA:

- identifies all the groups of claimed separate inventions which appear to lack unity a priori or a posteriori during or after searching the first invention, and invites the applicant *in the (and, as a rule, only) communication* pursuant to R40.1 PCT to pay the corresponding number of additional search fees; this invitation contains the mandatory “reasoned statement” and the above warning clause;
 - *subsequently, searches all the inventions identified in the R40.1 PCT communication for which search fees have been paid within the time limit;*
- when the further search results lead to an additional finding of lack of unity a posteriori of an invention:
 - restricts the search to the first of the newly detected inventions and indicates in a clear and unambiguous way in the international search report that only a part of the application has been searched.

Example (of a subsequent finding of lack of unity in PCT Chapter I)

If, in the first step, three groups of claimed non-unitary inventions (A, B and C) are identified, the examiner searches the first (A), and invites in a reasoned invitation additional search fees for the latter two (B and C).

(The invitation to pay additional fees is communicated on Form PCT/ISA/206).
After fees for groups B and/or C are paid, the ISA commences searching for B and/or C. If it finds prior art which gives rise to lack of unity (“a posteriori”) for further inventions B₁ to B_n, and if searching for these further inventions requires an non-negligible effort, this search is limited to B₁.

The search report (in cases of a subsequent finding of a lack of unity in PCT Chapter I)

A search report is drawn up for the inventions searched, with a reference to an annex, if needed for reasons of lack of space *on the existing form*, setting out that the ISA considers that at least one case of further lack of unity (“a posteriori”) is detected and that only a part of the application has been searched.

(Communicated on Form PCT/ISA/210)

In order to make the applicant aware of the risk that only a part of the application might be searched in case of successive findings of lack of unity, a standard warning clause is added to the reasoning of the invitation to pay additional search fees (in the continuation sheet of Form PCT/ISA/206, the “Invitation”). This clause appears whenever such an invitation is issued.

Information in Box II of Form PCT/ISA/210

In order to indicate clearly and unambiguously that and why only a part of the application has been searched, the information in Box II of Form PCT/ISA/210 (continuation of first sheet 1) is presented as follows

1. The inventions as presented in the Invitation to pay additional fees are listed in the upper part of BOX II (often merely a reference “see additional sheet”).
2. Neither checkbox 1. (i.e. “1.”) nor checkbox 3. in the central part of Box II are crossed.

Additional sheet

On the additional sheet (“FURTHER INFORMATION CONTINUED FROM PCT/ISA/210”) the following message appears.

This International Searching Authority found multiple (group of) inventions in this international application, as follows:

(listing of claims and subject descriptions as defined in PCT/ISA/206 annex)

A (claim(s) a, b, c.:)
B (claim(s) d, e, f.:)

C(claim(s)g,h,i:.....)

The applicant has received the invitation pursuant to Rule 40.1 PCT and has paid additional search fees for invention(s) A, B, C,....

The International Searching Authority considers that for the invention(s)

(list the relevant invention(s) as defined in PCT/ISA/206 -annex):

(claim(s)g,h,i:.....)

a further lack of unity in view of the prior art as disclosed in:

CC-A-NNNNNNN

(identify the closest prior art for that (those) subject(s) as retrieved during the continued search)

has been revealed during the search for those parts of the International Application which relate to inventions in respect of which additional fees have been paid.

Only subject -matter related to the first invention (“main invention”) in those parts (claims.....; subject -matter *in words*) thus identified has been the subject of a search.

This International Search Report has therefore been limited to:

(list the inventions and the first “sub” -invention(s) which have been searched)

(claim(s)a,b,c:.....)

(claim(s)d,e,f:.....)

(claim(s)g,h:.....)

The applicant’s attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT).

The applicant is advised that the International Preliminary Examining Authority is normally not to carry out a preliminary examination matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any International Preliminary Examination procedure.

THE PRIOR REVIEW PROCEDURE

- (i) The EPO acting as ISA or IPEA finds the claimed invention to be non-unitary according to Rule 13.1 PCT and invites the applicant to pay additional search fees according to Art. 17(3)(a) PCT and Rule 105(1) EPC or additional examination fees according to Art. 34(3)(a) PCT and Rule 105(2) EPC.
- (ii) The applicant pays additional search or examination fees to the EPO under protest, requesting the refund of some or all of the additional fees paid because she

contendseitherthattheapplicationisfullyunitaryorthatsomeoftheinventions
inrespectofwhic hhepaidfeesareunitarywitheachother.

- (iii) AccordingtoRule105(3)EPCtheEPOactingasISAorIPEAsubmitstheprotest
toapriorreviewoftheinvitationtopayadditionalsearchorexaminationfees
whichitissuedunder(i).Inthisreviewit ischeckediftheinvitationwasjustified
totheextentthatitisdisputedbytheapplicant(i.e.theEPOexaminesifanyof
thedisputedadditionalfeespaidbytheapplicantshouldberefundedaccordingto
Rule40.2(c)PCTorRule68.3(c)PCT).Thispriorreviewisnormallycarriedout
bya “reviewpanel” consistingoftheexaminerwhoissuedtheoriginal
invitation*,hisimmediatesuperior(director)andanominatedexpertinthefield
oflackofunity(seeOJ1992,pp547 etseq).

Theresultsofthe priorreviewarenotifiedtotheapplicant(Rule40.2(e)PCT).

*NotethatRule40.2(e)PCTandRule68.3(e)PCTdonotforbidtheexaminer
whoissuedtheoriginalinvitationfrombeinginvolvedinthe priorreview
procedure.Rule40.2(d)PCTandRule68.3(d)PCThowever,forbidhisorher
involvementinthesubsequentstep(see(iv)below).

- (iv) Ifthepriorreviewdoesnotgrantalladmissiblerequestsoftheapplicant(i.e.if
thereviewpaneldoesnotordertherefundallofthoseadditionalsearcho r
examinationfeeswhichwerepaidbytheapplicantandtherefundofwhichhe
requestedinhisprotest),thentheapplicantmaytakehisprotesttothe“threeman
board”,“specialinstance”orthethe“competenthigherauthority”mentionedinRule
40.2(c)PCT orRule68.3(c)PCT(theBoardofAppealoftheEPO).Theprotestis
onlyvalidiftheapplicantpaystheprotestfeetotheEPOwithinonemonthofthe
notificationofthedecisionofthepriorreviewunder(iii).

AccordingtoRule40.2(d)PCTandRule 68.3(d)PCTtheauthorityexaminingthe
protestatthisstage(theBoardofappealoftheEPO), cannotincludetheexaminer
whoissuedtheoriginalinvitationunder(i).Thisisinanycaseextremelyunlikely.

- (v) WheretheEPOBoardofAppealfindsthe protest entirelyjustified,itwillrefund
theprotestfeepaidunder(iv)(Rule40.2(e)PCTandRule68.3(e)PCT).This
meansthatwheretheBoardofAppealrefundsallofthesesearchorexamination
feestherefundofwhichwasrequestedbytheapplicant inhisprotest,theBoard
willalsoordertherefundoftheprotestfee.However,wheretheBoardofAppeal
orderstherefundofonlysomeofthesesearchorexaminationfeestherefundof
whichwasrequestedbytheapplicantinhisprotestorwheretheBoa rdupholdsthe
decisionofthereviewpanelinfull,thennorefundoftheprotestfeeisduebecause
theprotestwasnot entirelyjustified.

[EndofAnnexIIandofdocument]