

PCT/GL/ISPE/4 PROV. 2 ORIGINAL: ENGLISH DATE: MAY 22, 2015

PATENT COOPERATION TREATY (PCT)

PCT INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES

(Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications Under the Patent Cooperation Treaty)

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- 1. This document sets out proposed modifications of the PCT International Search and Preliminary Examination Guidelines for the purposes of information to International Searching and Preliminary Examining Authorities under the PCT of the text of the Guidelines to be promulgated as PCT/GL/ISPE/4. The presently applicable text of the Guidelines, as in force from July 1, 2014, is as set out in document PCT/GL/ISPE/3, is available, on WIPO's web site at http://www.wipo.int/pct/en/texts/gdlines.html.
- 2. The general background and explanation for the proposed modifications, and the invitation to International Authorities to provide comments by June 22, 2015, are set out in Circular C. PCT 1455. The proposed modifications have already received consideration of some kind by the International Authorities, whether by way of discussion in sessions of the Meeting of International Authorities under the PCT ("PCT/MIA") or by way of PCT Circulars sent to Authorities by the International Bureau, including Circular C. PCT 1371, dated January 31, 2013 and C. PCT 1428, dated December 5, 2014. Such previous consideration was indicated in Explanatory Notes included as footnotes in documents PCT/GL/ISPE/3 Prov. and PCT/GL/ISPE/4 Prov.1 referred to in these Circulars.
- 3. The footnotes in the present document, made available to International Authorities through the Quality Subgroup electronic forum show the issues where there is no clear

agreement between International Authorities. The International Bureau invites Authorities to study these issues and make further proposals to a future session of the PCT/MIA. ^{1, 2}

4. It is intended that the modified text of the Guidelines will be promulgated as document PCT/GL/ISPE/4 shortly after the reply date for Circular C. PCT 1455, superseding document PCT/GL/ISPE/3.

EXPLANATORY NOTES:

The footnotes appearing in this document are explanatory in nature and do not form part of the text of the Guidelines themselves. The footnotes will be deleted before the final version of the modified Guidelines is promulgated.

Proposed additions to the text of the Guidelines compared to document PCT/GL/ISPE/3 are <u>underlined</u> and proposed deletions are <u>struck through</u>. Text that has been modified in response to the comments received to document PCT/GL/ISPE/4 Prov.2 annexed to Circular C. PCT 1428 is <u>highlighted</u>. Renumbering of paragraphs consequent on the insertion of new paragraphs or deletion of existing paragraphs is not, in general, specifically indicated.

PCT INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES (as in force from)

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PART I INTRODUCTION AND OVERVIEW

Chapter 1 Introduction

Purpose and Status of These Guidelines

- 1.01 These Guidelines give instructions as to the practice to be followed by Authorities during the international search and examination procedures.
- 1.02 The Guidelines are addressed primarily to the examiners in the various International Searching and Preliminary Examining Authorities but it is hoped that they will also be of assistance to applicants and patent practitioners. They also apply, where appropriate, to international-type searches (see paragraph 2.22). Moreover, the Guidelines may be useful to the patent Offices of the designated and elected States in the national phase in the searching and examination of the international application and in better understanding the international search and examination reports. Although the Guidelines deal with international applications, they may be used mutatis mutandis by national Offices in dealing with national applications if the national law so permits; also they may be used in revising national laws with the purpose of unification of current practices in patent Offices of various countries. They, however, do not generally cover the actions of the receiving Office, even though this might in some cases be the same Office as the International Searching Authority and/or the International Preliminary Examining Authority.

Articles 16(3)(b), 32, 33

- 1.03 These Guidelines are common rules of international search and examination that provide instructions regarding international search and examination and assist in the application of the provisions of the PCT. PCT Regulations and PCT Administrative Instructions relating to international search and examination. They are intended to cover typical occurrences. They should therefore be considered only as general directives; examiners will have to go beyond the instructions in exceptional cases. Nevertheless, applicants can expect the International Searching and Examining Authorities to act, as a general rule, in accordance with the Guidelines until such time as they are revised. In addition, at various points throughout these Guidelines, the examiner is directed to interpret a claim in a particular fashion. This has been done to enable the designated and/or elected Offices to understand the examiner's conclusion as to novelty, inventive step (nonobviousness) and industrial application, and in no way binds the designated and/or elected Offices to adopt a similar interpretation. The Guidelines also set forth standards for quality for the International Searching Authorities and the International Preliminary Examining Authorities to follow so as to minimize differences in the results of the search and examination process among the various Authorities.
- 1.04 The above criteria merely serve the purpose of international search and preliminary examination, and any Contracting State may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable. It should be noted also that the Guidelines do not have the binding authority of a legal text. These Guidelines have been designed to assist International Searching and Examining Authorities in establishing international search and examination reports, in accordance with PCT Articles 17 and 18, written opinions in accordance with PCT Article 34 and Rule 43bis and international preliminary examination reports in accordance with PCT Article 35. For the ultimate authority on questions concerning international search and examination, it is necessary to refer to the PCT Articles themselves, interpreted, where necessary, by reference to the Minutes of the Washington Diplomatic Conference and interpretations given by the PCT Assembly. Any failure of an International Searching or Examining Authority to follow these Guidelines would not of itself constitute a basis for review of the action of the

Authority except where such review is provided for under the applicable national law and practice.

Arrangement and Terminology of These Guidelines

- These Guidelines initially set out the framework, which is to be followed at the international search stage and the international preliminary examination stage and then go on to set out a number of steps and concepts in greater detail. The Guidelines are divided into eight parts. Part I provides a brief overview of the procedures at the international search stage and international preliminary examination stage. Part II provides details of the international application. Part III provides details of considerations that the examiner needs to keep in mind during both the international search stage and the international preliminary examination stage. Part IV provides details on the international search. Part V contains information on the content of written opinions and the international preliminary examination report. Part VI discusses procedures during the international preliminary examination. Part VII provides for a common quality framework, and Part VIII discusses clerical and administrative procedures. Some of the chapters in the various parts are relevant to only one stage or the other. However, with a few exceptions which are explained in the text, where examiners in the International Searching Authority and the International Preliminary Examining Authority consider any particular issue, this should be done to the same standards and most chapters are relevant to the work of both stages.
- 1.06 Unless qualified, references in the Guidelines to "the Treaty" are to the PCT, to "Articles" are to those of the Treaty, to "Rules" to those of the Regulations under the PCT, to "Sections" to those of the Administrative Instructions under the PCT, and to "parts," "chapters" and "paragraphs" to those of these Guidelines. References to Parts and Annexes of the Administrative Instructions under the PCT bear the prefix "Al".
- 4.051.07 "International Authority" or "Authority", unless qualified, mean International Searching Authority and/or International Preliminary Examining Authority, as the case requires. The term "examiner," unless qualified, is used in the Guidelines to refer to the examiner working in the International Preliminary Examining Authority, or the examiner working in the International Searching Authority or the Authority specified for supplementary international search. "Search" and "examination", unless qualified, mean international search and international preliminary examination according to the Treaty and Regulations.
- 1.061.08 References to a "national" Office or law, include also regional systems where several States have entrusted to an intergovernmental authority the task of granting regional patents.

Overview of International Application Process

1.071.09 The procedure through which an international patent application under the Patent Cooperation Treaty proceeds from the filing of the application to the granting of a patent (or the refusal thereof) comprises two main stages, commonly referred to as the "international phase" and the "national phase" (or "regional phase" when an international application comes before a regional body rather than a national one). As indicated in paragraph 1.01, a major change to processing international applications is that the International Searching Authority rather than the International Preliminary Examining Authority establishes a first written opinion (under PCT Rule 43bis), thus combining the international search and international preliminary procedures to a much greater extent than before. The following paragraphs 1.10, and 1.11, and the flowchart of typical international application processing that has been provided at the end of this chapter, provide a brief overview of the international phase, with a complete explanation provided in Parts 2 through 8 parts II to VIII of the Guidelines.

Articles 22, 23

- 4.081.10 The international phase begins when the international application is filed and, provided that the international application is not withdrawn, includes various formalities checks, an international search, preparation of a written opinion, publication of the application and, optionally, an international preliminary examination. During this phase, no national or regional Office may process or examine the application except at the specific request of the applicant.
- 4.091.11 The international phase in turn includes a number of groups of actions which are distinct in nature, though they may in practice overlap slightly in timing:
- (a) Filing of the international application with an appropriate receiving Office: this includes a "request" (a petition that the international application be processed according to the Treaty, together with certain data concerning matters such as the applicant, inventor, any agent and formal details about the application, such as the title and any priority claims), a description, one or more claims, one or more drawings (where required) and an abstract;
- (b) Certain procedural checks are carried out, an international filing date is accorded and copies of the application are sent to the International Bureau (the record copy) and the International Searching Authority (the search copy);
- (c) An international search by the International Searching Authority: this includes a search for earlier disclosures relevant to the novelty and inventive step of the claimed invention and the establishment of an international search report and a written opinion on novelty, inventive step and industrial application, normally at 16 months from the priority date, as detailed later in this document. (See Chapter 2 and Parts IV and V);
- (d) International publication of the international application, the international search report, and Article 19 amendments (if any) by the International Bureau at 18 months from the priority date; the written opinion of the International Searching Authority (and any informal comments filed by the applicant) will be made available to the public at the same time;
- (e) Optionally, at the request of the applicant, a supplementary international search by a participating Authority other than the one which conducted the main international search, in order to extend the overall scope of the search (for example, to better cover prior art in languages not covered by the main Authority). Supplementary international searches may be requested from more than one participating Authority. For a more detailed outline of the supplementary international search procedure, see Chapter 15 at paragraphs 15.75 to 15.97 and also paragraphs 9.42 and 16.03.
- (d)(f) Optionally, at the request of the applicant by filing a "demand" (Chapter II of the PCT), an international preliminary examination conducted by the International Preliminary Examining Authority, in which the examiner considers further the issues of novelty, inventive step and industrial application, taking into account any comments or amendments under Article 19 or 34 from the applicant, as detailed later in this document; this concludes with the establishment of an international preliminary examination report, which is entitled "international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)" (see Chapter 17).
- (e)(g) Issuance of an "international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)" by the International Bureau on behalf of the International Searching Authority if the applicant does not file a demand requesting examination of the international application in response to the written opinion as established by the International Searching Authority; such an the international preliminary report on patentability has the same content as the written opinion established by the International Searching Authority.
- (f)(h) Distribution by the International Bureau of documents to the designated Offices or elected Offices, including copies of the application, any amendments which have been

filed, any supplementary international search reports(s), and an international preliminary report on patentability, comprising either the contents of the written opinion by the International Searching Authority or, where established, the international preliminary examination report.

The National (or Regional) Phase

4.101.12 After 30 months from the priority date of the application (20 months in certain States due to transitional provisions; States also have the option of specifying a later date applicable for applications before their Office), the application may begin its national (or regional) phase in each designated Office (if international preliminary examination has not been demanded and Chapter I of the PCT applies) or elected Office (if international preliminary examination has been demanded and Chapter II of the PCT applies). This is the procedure which actually leads to the grant, or refusal, of a patent according to the relevant national law or regional arrangement. While the national and regional Offices may not make further requirements beyond those of the Treaty and Regulations in respect of matters of form and contents, they are not bound by the Treaty to follow the results of any international search or examination which has been performed when the application is examined during the national or regional phase.

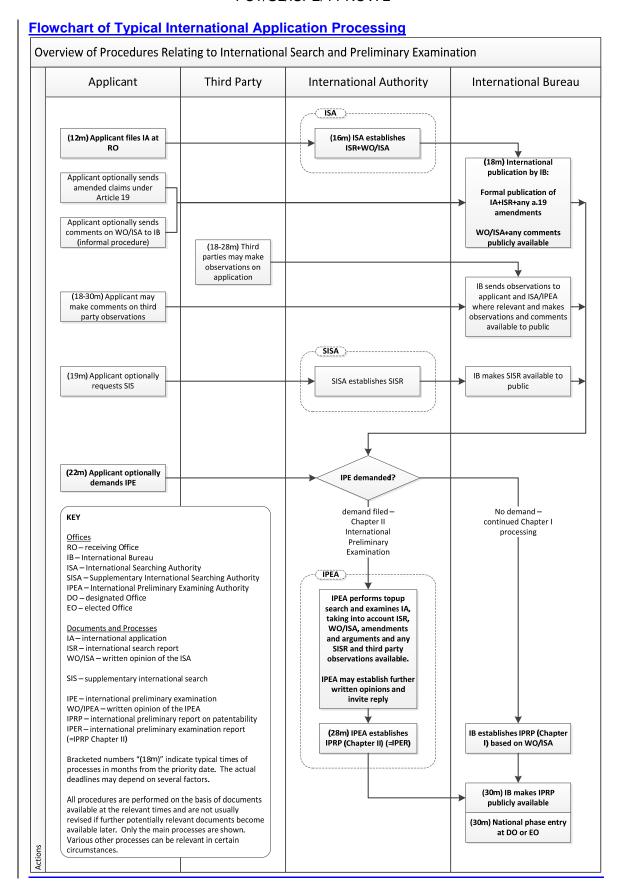
The International Authorities

Articles 16, 32; Rules 35, 36, 59, 63

1.13 The International Searching Authorities and International Preliminary Examining Authorities are national Offices or intergovernmental organizations entrusted with a number of tasks under the Treaty, especially the establishment of international search and preliminary examination reports. Authorities are appointed by the Assembly of the PCT Union. The requirements for appointment are such that Authorities must necessarily be appointed in both capacities (that is, to undertake both search and preliminary examination). Details about the functions of Authorities and the requirements of particular Authorities are set out in Annexes D, E and SISA of Volume I of the PCT Applicant's Guide. The Authorities meet together regularly in sessions of the Meeting of International Authorities under the PCT (PCT/MIA) (see WIPO's web site via http://www.wipo.int/pct).

4.111.14 One or more Authorities may be competent to search or examine a particular international application. This depends on agreements between the International Authorities and the International Bureau, together with a decision which has been notified to the International Bureau by each receiving Office concerning which Authorities are competent to act in respect of international applications filed with that Office. Where more than one Authority might be competent to perform the search or examination of any particular application, the applicant chooses the desired Authority in the request or demand. International Searching Authorities may each decide whether they wish to offer a supplementary international search service, which will then normally be available to any applicant for whom that Authority did not perform the main international search.

1.121.15 The International Preliminary Examining Authority for any particular application will usually be the same body as the International Searching Authority, but this is not necessarily the case. A different Authority may be specifically chosen by the applicant or else, occasionally, an Authority may be competent to search a particular international application but not to examine it. Consequently it is particularly important that both the international search report and the written opinion by the International Searching Authority are produced to consistent standards, so that they may be used effectively by any other Authority, as well as by applicants and designated Offices.



Chapter 2 Overview of the International Search Stage

Objectives

2.01 This chapter provides a brief, introductory overview of the international search stage. A complete discussion of the procedure at the international search stage is provided in Parts II and IV of the Guidelines.

Article 15(2); Rule 33.1(a)

2.02 The objective of the international search is to discover the prior art which is relevant for the purpose of determining whether, and if so to what extent, the claimed invention to which the international application relates is or is not novel and does or does not involve an inventive step. In some cases the International Searching Authority is not required to establish a search for some or all of the claimed subject matter, either because the scope of the claims is too uncertain or the application covers excluded subject matter (see Chapter 9) or else more than one invention is claimed (see Chapter 10).

Rule 43bis

- 2.03 At the same time as establishing the international search report, the search examiner establishes a written opinion as to whether the claimed invention appears to be novel, involve an inventive step, be industrially applicable and meet with the other requirements of the Treaty which are checked by the International Searching Authority. The written opinion has the primary objective of formulating a preliminary and non-binding opinion on the questions of whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable. A secondary objective is to identify whether there appear to be any defects in the form or contents of the international application, for example with regard to the clarity of the claims, the description, and the drawings, or whether the claims are fully supported by the description.
- 2.04 It is essential that the search and the written opinion are carried out according to the same criteria which are used during the international preliminary examination. The search may also report on some material which may not strictly be relevant to novelty and inventive step, as detailed below in paragraph 2.10.

Preliminary Matters

Receipt of Search Copy from Receiving Office

Rule 23.1

2.05 Provided that the international application has been filed in a language accepted by the International Searching Authority, the receiving Office sends the search copy of the application to the International Searching Authority (and the record copy to the International Bureau) as soon as it has allocated an identification number and performed the relevant formalities checks under Articles 11 and 14 and the international search fee has been paid.

Rule 12

- 2.06 Where the language in which the international application is filed is not accepted by the International Searching Authority that is to carry out the international search, the applicant must furnish to the receiving Office a translation of the international application into a language which is all of the following:
 - (a) language accepted by the International Searching Authority, and
 - (b) a language of publication, and
- (c) a language accepted by the receiving Office under Rule 12.1(a), unless the international application is filed in a language of publication.

However no such translation is required of the request or any sequence listing part of the description. Where the applicant is required to furnish such a translation, the international search will be carried out on the basis of that translation.

Rule 23.1(b)

2.07 Where a translation of the international application is furnished to the receiving Office under Rule 12.3, a copy of that translation and of the request are together considered to be the search copy; that search copy is transmitted by the receiving Office to the International Searching Authority promptly upon receipt from the applicant except where no search fee has been paid. In the latter case, the search copy is transmitted promptly after payment of the search fee.

Acknowledgement and Allocation by the International Searching Authority

Rule 25.1

- 2.08 The International Searching Authority notifies the applicant that the search copy has been received using Form PCT/ISA/202 and sends a copy of the notification to the International Bureau and, where this is not the same as the International Searching Authority, the receiving Office.
- 2.09 The international search is then assigned as quickly as possible to a search examiner who is capable of completing the search within the time limit. The preliminary classification must also be determined as quickly as possible.

The International Search Process

- 2.10 The role of the International Searching Authority is as follows, the details being considered in subsequent chapters referred to below:
- (a) to determine classification of the case, particularly to determine whether examiners specializing in other fields need to be consulted to ensure a proper search is carried out; this classification may need to be reconsidered in the light of fuller consideration, but a definitive classification must be made by the time that the international application is published (see Chapter 7);

Article 17(3); Rule 40

(b) to consider whether the application meets the requirement of unity of invention and, if not, whether the applicant should be invited to pay further search fees relating to the extra inventions (see Chapter 10);

Rule 39

(c) to consider whether some or all of the subject matter relates to subject matter which the Authority is not required to search (see Chapter 9);

Rules 4.4112, 16.3, 41

(d) to determine whether to use the results of any earlier search, referred to by the applicant in the request Form relating to the application, to establish the international search report, and to consequently authorize any appropriate refund;

Rule 13ter

(e) to determine whether to invite the applicant to provide a listing if the international application contains disclosure of one or more nucleotide and/or amino acid sequences but does not include a sequence listing in compliance with the paper form or computer-readable sequence listing standards standard for sequence listings in paper or electronic form provided for in the Administrative Instructions (see paragraphs 15.12 and 15.13);

Articles 15, 17(2)

(f) to perform an international search to discover relevant prior art (see Chapter 11) taking into account that there may be subject matter such that the Authority is not obliged to search where the subject matter is such that the Authority is not obliged to do so (see Chapter 9), the description, claims or drawings fail to comply with the prescribed requirements to such an extent that no meaningful search could be carried out, (see Chapter 9 and paragraph 15.33) or else the claims relate to several different inventions and additional search fees, which the Authority has invited the applicant to pay, have not been paid (see Chapter 10);

Rules 37, 38

(g) to consider whether the abstract and title are appropriate and, in certain circumstances, to draft alternatives, (see paragraphs 16.33 to 16.47);

Rule 43

(h) to establish a search report, indicating the results of the search and certain other information (see Chapter 16), or else make a declaration that a search was either not required or would not be meaningful (see Chapter 9);

Rule 43bis

- (i) to establish a written opinion as to whether the international application appears to be novel, to involve an inventive step, to be industrially applicable and to comply with other requirements of the Treaty and Regulations insofar as they are checked by the International Searching Authority (see Chapter 17).
- 2.11 Some of the above matters, especially unity of invention, may be the subject of ongoing consideration, depending on the outcome of the search. Nevertheless it is important to consider matters at an early stage in view of the limited time available in which to obtain corrections or additional fees from the applicant.
- 2.12 In a few situations leading up to the establishment of the international search report, the International Searching Authority may specifically invite a response, such as where the international application is considered to lack unity of invention (see Chapter 10) in which case additional fees may be required to be paid for searching the other invention(s), either under protest together with a reasoned statement or without a protest. The International Searching Authority may, also, require a protest fee for the examination of the protest.

Time Limit for Establishing International Search Report

Rules 42.1, 43bis.1

- 2.13 The International Searching Authority must establish the international search report (or a declaration made that the International Searching Authority is not required to perform a search or cannot perform a meaningful search) and written opinion within:
 - (i) three months from the date of receipt of the search copy, or
 - (ii) nine months from the priority date of the application,

whichever time limit expires later.

Transmittal of the International Search Report, Written Opinion, etc.

Rule 44.1

2.14 Once the international search report and written opinion are established, the International Searching Authority transmits one copy of each to the International Bureau and one copy to the applicant on the same day.

Options Open to the Applicant

- In general, the applicant has the following options available following the receipt of the international search report and written opinion of the International Searching Authority:
- (a) send (informal) comments on the written opinion of the International Searching Authority to the International Bureau, who will make these available to the public and to designated Offices (see paragraphs 2.17 and 2.18, below);

Rule 46

(b) submit to the International Bureau amendments of the claims under Article 19(1) accompanied by a letter drawing attention to the differences between the claims and indicating the basis for the amendments in the application as filed, and optionally including a brief statement explaining the amendments;

Rule 45bis

(c) request one or more supplementary international searches from Authorities which offer that service, other than the Authority which performed the main international search;

Articles 31, 34(2)(b); Rule 53

- (d) request international preliminary examination, including arguments and/or amendments which will be taken into account by the International Preliminary Examining Authority;
 - (e) withdraw the application under Rule 90bis; or
- (f) take no further action in the international phase, instead waiting until it is necessary, or desired, to pursue the application before designated Offices.

Further Processing of the International Search Report and Written Opinion

Confidential Treatment

Article 30; Rule 94.3

2.16 Prior to the international publication of the international application, all matter pertaining to the application is confidential and may not, without the request or authorization of the applicant, be accessed by any person or authority, except for the transmissions of information specifically required by the Treaty and Regulations for the purposes of processing the application.

If early processing is requested, the designated or elected Office may allow access to any documents which have been communicated to it to the extent provided by its national law, provided that the international application has been published.

Publication of the Search Report and Making Available of the Written Opinion of the International Searching Authority

Article 21(3); Rule 48.2, 44ter

2.17 The international search report is published with When the international application is published by the International Bureau, the international search report is published with the pamphlet unless it is not yet available. (or, if If delayed, it is published separately as soon as possible afterwards. The written opinion and any informal comments filed by the applicant will be made available to the public by the International Bureau at the same time. as the international publication..

Transmission and Making Available of the International Preliminary Report on Patentability (Chapter I of the PCT) (When no Demand Is Filed)

Rule 44bis

2.18 If no international preliminary examination report is to be established because the applicant did not file a demand for preliminary examination, or the demand has been withdrawn, the International Bureau will prepare a report, entitled "international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)" having the same contents as the written opinion. Note that even if the applicant filed any amendments under Article 19, the amendments will not be taken into consideration in the international preliminary report on patentability. Also, note that in certain circumstances as set forth in Rule 44bis.3(a) and (d), the International Bureau may translate the written opinion or report into English. Any such report and translation is communicated to designated Offices, who may then allow access to it, after 30 months from the priority date, or earlier if the applicant has requested early national processing of his application under Article 23(2). The report together with any translation will also be made available to the public by the International Bureau after 30 months from the priority date.

<u>Copies of Documents Cited in Search Report</u>Further Responsibilities of the International Searching Authority

Article 20(3), Rule 44.3

2.19 At any time within seven years of the international filing date of the international application, either the applicant or any designated Office is entitled to request copies of the documents cited in the search report to be sent to them by the International Searching Authority, subject, if required by the Authority, to the payment of costs for preparing and mailing the copies (the applicant may be sent copies of the citations automatically with the international search report).

Supplementary International Searches

Rule 45bis

- 2.20 International Searching Authorities may offer supplementary international searches as an optional additional service for applicants. Such searches are intended as a complement to the main international search, recognizing the fact that no search can be completely exhaustive. A supplementary search may be particularly relevant where the Authority conducting it has language specialization that is not available in the Authority conducting the main international search. The applicant can request a supplementary search from any Authority which offers the service (except the Authority conducting the main search) at any time before 19 months from the priority date. More than one supplementary search may be requested from different Authorities offering the service.
- 2.21 Many of the details of the service provided are decided by the Authority which is to carry out the supplementary search. The scope of the service is set out in an annex to the agreement between the International Bureau and the Authority, and details are published in Annex SISA of the PCT Applicant's Guide. Features of the supplementary search procedure, including conditions, limitations and time limits, are discussed in more detail in paragraphs 15.76 to 15.97 and also in paragraphs 9.42 and 16.03.

International-Type Searches

Article 15(5)

2.22 Under Article 15(5), an International Searching Authority may be entrusted with carrying out "international-type searches" for national applications. These searches are by definition similar to international searches, and the same considerations for establishing the search report will apply. However, only the search itself is carried out; no written opinion is established for such applications unless there is a specific arrangement between the Offices involved for such an opinion to be established at the same time.

Chapter 3 Overview of the International Preliminary Examination Stage

Introduction

3.01 This chapter provides a brief introductory overview of the international preliminary examination stage. A complete discussion of the procedure at the international preliminary examination stage is provided in Parts V and VI of the Guidelines.

Article 31

3.02 International preliminary examination is an optional part of the processing of an international application, performed if the applicant files a "demand." It shares the objectives of, and builds on the process of, the written opinion of the International Searching Authority, allowing the applicant to respond to the International Preliminary Examining Authority, with arguments as to why the opinion was incorrect, and/or with amendments to attempt to overcome objections. It has the primary objective of formulating a preliminary and non-binding opinion on the questions of whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable. A secondary objective is to identify whether there appear to be any defects in the form or contents of the international application, for example with regard to the clarity of the claims, the description, and the drawings, or whether the claims are fully supported by the description. The results of the international preliminary examination are recorded in the international preliminary examination report (entitled "international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)"), copies of which are then sent to the applicant and the International Bureau. The International Bureau communicates the report to each elected Office (that is, usually, the Offices of all Contracting States).

Article 31(4); Rule 53.7

- 3.03 Filing of a demand constitutes the "election" of all States which were designated when the international application was filed, which have not been withdrawn and which are bound by Chapter II of the Treaty (at the time of writing this included all Contracting States). Election indicates an intention to use the results of the international preliminary examination in the relevant States, but it should be remembered that the results of international preliminary examination are not binding on the States.
- 3.04 Using international preliminary examination has the practical effect that national processing starts under much more advantageous conditions both for the applicant and the national Offices than would be the case without the PCT. The applicant has, thanks to the written opinion done inprepared under Chapter I, an earlier and stronger indication of his chances of obtaining protection. Moreover, amendments made in the international phase in response to the written opinion may be reflected in the international preliminary examination report and need not be filed in each elected State. The elected Offices save a considerable amount of the effort of examination. The exact extent of the saving depends on the national law and practice.
- 3.05 The attitude of the examiner is very important. He should always try to be constructive and helpful. He should bear in mind that, subject to the requirements of the PCT, the drafting of the description and claims of an international application is the responsibility of the applicant or his authorized representative.
- 3.06 All international applications, regardless of their country of origin and the language in which they are written, should receive equal treatment.

Preliminary Matters

Filing of Demand

Article 31(6); Rule 54bis

3.07 The applicant should file the demand with the competent International Preliminary

Examining Authority before the expiration of the later of the following time limits:

- a. three months from the date of transmittal to the applicant of the international search report or the declaration referred to in Article 17(2)(a), and the written opinion established under Rule 43bis.1, or of the declaration referred to in Article 17(2)(a); or
 - b. 22 months from the priority date of the international application.
- 3.08 For transitional purposes, applicants should note that they must file the demand within 19 months of the priority date if they wish to gain the benefit of a 30-month international phase for the purposes of certain States which have made reservations with respect to modifications to Article 22(1), which came into force for most States on April 1, 2002. The States which notified a reservation in respect of this modification were published in PCT Gazette No. 08/2002, February 21, 2002. Subsequent withdrawals are also published in the PCT Gazette. Information may be obtained from the WIPO web site at www.wipo.int/pct.

Checking of Demand and Notification of Receipt

Rules 54bis, 59, 60, 61

3.09 The International Preliminary Examining Authority checks to ensure that it is competent to act as Authority for that application and that the demand is in the correct form and language, and was filed within the time limits specified in paragraph 3.07. If the Authority is not competent, it transmits the demand to the International Bureau; if there are any defects, the applicant is invited to correct them; if the demand was filed after the expiration of the period set in paragraph 3.07, it is considered not to have been made, and the International Preliminary Examining Authority so informs the applicant. If the demand is in order, the Authority indicates the date of receipt on the demand, transmits a copy to the International Bureau and notifies the applicant of receipt of the demand. These procedures are set out in detail in Chapter 18.

Rule 62

- 3.10 The International Bureau will then send the International Preliminary Examining Authority:
- (a) a copy of the written opinion established by the International Searching Authority, unless the national Office or intergovernmental organization that acted as International Searching Authority is also acting as International Preliminary Examining Authority; and
- (b) a copy of any amendments filed under Article 19 and any statement explaining the amendments and any impact that they might have on the description and drawings, unless the Authority has indicated that it has already received these.

Rule 62bis.1

3.11 If the written opinion of the International Searching Authority was not established in English or a language accepted by the International Preliminary Examining Authority, that Authority may request the International Bureau to translate the opinion into English. The translation is established within two months and copies sent to both to the International Preliminary Examining Authority and to the applicant, who may make written comments on the correctness of the translation and send them to the International Bureau and the International Preliminary Examining Authority.

Article 31(7); Rule 61

3.12 Upon receipt of the demand from the International Preliminary Examining Authority, the International Bureau also notifies elected Offices of their election and publishes information on the demand in the Gazette, though this does not occur prior to publication of the international application.

Commencement of International Preliminary Examination

Rule 69.1

- 3.13 The International Preliminary Examining Authority normally starts the international preliminary examination (see Chapter 19) when:
 - (a) it is in possession of:
 - (i) the demand;
- (ii) the amount due (in full) for the handling fee and the preliminary examination fee, including, where applicable, the late payment fee under Rule 58*bis.*2; and
- (iii) if the applicant is required to furnish a translation under Rule 55.2, that translation; and
- (iv) either the international search report <u>or the declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be <u>established</u>, and the written opinion established under Rule 43*bis*.1 or a notice of the <u>declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established</u>;</u>

and

- (b) the time limit within which the applicant was permitted to file the demand (see paragraph 3.07) has expired, or earlier if the applicant has expressly requested an earlier start.
- 3.14 The exceptions to the above are as follows:

Rule 69.1(c)

(a) Where the statement concerning amendments contains an indication that amendments under Article 19 are to be taken into account (Rule 53.9(a)(i)), the International Preliminary Examining Authority does not start the international preliminary examination before it has received a copy of the amendments concerned.

Rule 69.1(e)

(b) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority does not start the international preliminary examination before it has received the amendments or before the time limit fixed in the invitation referred to in Rule 60.1(g) (see paragraph 18.04) has expired, whichever occurs first.

Rule 69.1(b), (d)

- (c) If the national Office or intergovernmental organization that acts as International Searching Authority also acts as International Preliminary Examining Authority in respect of an application, the international preliminary examination may, if that national Office or intergovernmental organization so wishes, start at the same time as the international search (subject to the possible need to invite the applicant to provide copies of amendments under Article 34, as noted in paragraph (b), above), provided that applicant has not indicated (under Rule 53.9(b)) in the statement of amendments that the examination is not to be postponed until after the expiry of the time limit for filing amendments under Article 19 (such amendments only being permitted after the international search report has been received).according to the statement concerning amendments (see paragraphs (c) and (d) below).
- (b) Where the statement concerning amendments contains an indication that amendments under Article 19 are to be taken into account (Rule 53.9(a)(i)), the International Preliminary Examining Authority does not start the international preliminary examination before it has received a copy of the amendments concerned.

- (d) Where the statement concerning amendments contains <u>such</u> an indication that the start of the international preliminary examination is to be postponed (Rule 53.9(b)), the International Preliminary Examining Authority does not start the international preliminary examination before until whichever of the following occurs first:
 - (i) it has received receives a copy of any amendments made under Article 19;
- (ii) it has received receives a notice from the applicant that he does not wish to make amendments under Article 19; or
- (iii) the time limit under Rule 46.1 for filing Article 19 amendments expires. the later of three months from the transmittal of the international search report and written opinion or of the declaration that no international search will be established; or the expiration of 22 months from the priority date.
- (d) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority does not start the international preliminary examination before it has received the amendments or before the time limit fixed in the invitation referred to in Rule 60.1(g) (see paragraph 18.04) has expired, whichever occurs first. These examination procedures before the International Preliminary Examining Authority are set out in detail in chapter 19.
- 3.15 As soon as examination is to begin, the international application is sent to an examiner, who is responsible for establishing the international preliminary examination report. Where the International Searching Authority which carried out the search and the International Preliminary Examining Authority are part of the same national Office, the international preliminary examination should preferably be performed by the examiner who did-was responsible for the international search.

The International Preliminary Examination Process

Rule 66.1ter

3.16 The International Preliminary Examining Authority carries out a top-up search normally at the start of the international preliminary examination process. The main objective of the top-up search is to discover relevant documents referred to in Rule 64 that became available for search after the establishment of the international search report. No top-up search is carried out if the Authority considers that such a search would serve no useful purpose (see paragraph 19.15).

Article 34(2)

- 3.17 The applicant generally has the right to receive at least one written opinion, essentially directed to the questions of whether the claimed invention is novel, involves an inventive step (is non-obvious) and is industrially applicable, prior to the report being established unless the International Preliminary Examining Authority considers that all of the following criteria are fulfilled:
- (i) the invention satisfies the criteria set forth in Article 33(1), that is that it appears to be novel, involve an inventive step and have industrial application, as defined for the purposes of the Treaty;
- (ii) the international application complies with the requirements of the Treaty and the Regulations which are checked by the International Preliminary Examining Authority (see Rule 70.12 and Chapter 17); and
 - (iii) the Authority does not intend to make other permitted observations.

Article 33(6); Rules 45bis.8(c)Rule 66.1(e: Section 420)

3.18 Copies of the international search report and of any supplementary international search report are transmitted by the International Bureau to the International Preliminary Examining Authority. All documents cited in the international search report and supplementary international search report are taken into consideration during the

international preliminary examination, together with any other documents considered to be relevant. However the The International Preliminary Examining Authority is not obliged to draw up a written opinion on any claims for which an international search report has not been established. A supplementary search report need not be taken into account by the Authority for the purposes of a written opinion or the international preliminary examination report if the supplementary search report is received by the Authority after it has begun to draw up the written opinion or examination report (Rule 45bis.8(c)).

Rule 66.1bis

3.19 Furthermore, it should be noted that the written opinion established by the International Searching Authority under Rule 43bis.1 (see paragraph 2.10(i)) is usually considered to be the first written opinion of the International Preliminary Examining Authority for this purpose. The exception to this rule is that International Preliminary Examining Authorities may notify the International Bureau that written opinions established by specified International Searching Authorities (other than by that International Preliminary Examining Authority acting in its role as an International Searching Authority) shall not be considered to be a written opinion for this purpose. When this applies to a particular application, the Authority must notify the applicant accordingly in writing. The Authority should also in any case take the International Searching Authority's opinion into account when establishing its own written opinion.

Basis of the Written Opinion or International Preliminary Examination Report

Rule 66

- 3.20 The applicant is entitled to file amendments under Article 34, which will be taken into account for subsequent written opinions and the international preliminary examination report, as will any amendments which were made under Article 19, unless they are reversed or superseded by those later made under Article 34 or the applicant fails to complz with Rule 46.5(b)(iii) or Rule 66.8(a) when filing these amendments (in particular where he fails to indicate the basis for the amendments filed in the application as originally filed. The details of permissible amendments are set forth in Chapter 20 at paragraphs 20.04 et seq.
- 3.21 The written opinion established under Rule 43bis.1 will however include a notification including a time limit for response in the event that it is treated as the first written opinion of the International Preliminary Examining Authority. The consequence of this is that it will usually be necessary for amendments or arguments to be filed at the same time as the demand in order to ensure that they are taken into account during international preliminary examination.

Further Consideration

Rules 66.2, 66.4, 66.6

3.22 Where the International Preliminary Examining Authority has carried out a top-up search and intends to raise objections based on prior art documents discovered in the top-up search, a further written opinion should be issued. In other cases, the International Preliminary Examining Authority may, at its discretion, issue further written opinions provided that sufficient time is available, that the applicant makes an effort to meet the examiner's objections and provided that the Authority has sufficient resources to provide such services. The Authority may also communicate informally with the applicant in writing, by telephone or by personal interview.

Nature of the International Preliminary Examination Report

Article 35(2); Rule 70

3.23 The report issued by the Authority does not contain any statement on the question whether or not the claimed invention is or seems to be patentable according to the law of any country; it merely states, by a "Yes" or "No", in relation to each claim whether such claim seems to satisfy the said three criteria and each such statement is accompanied by citations and other explanations.

Time Limit for Establishing the International Preliminary Examination Report

Rules 69.2; 70.15(b)

- 3.24 The International Preliminary Examining Authority must establish an international preliminary examination report, entitled "international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)," within whichever of the following periods expires last:
 - (i) 28 months from the priority date;
- (ii) six months from the time provided under Rule 69.1 for the start of the international preliminary examination (see paragraphs 3.13 to 3.14); or
- (iii) six months from the date of receipt by the International Preliminary Examining Authority of any translation furnished under Rule 55.2 (see paragraphs 18.11 and 18.12).

Transmittal of the International Preliminary Examination Report

Rule 71.1

3.25 The report is transmitted by the International Preliminary Examining Authority to both the applicant and the International Bureau.

Further Processing of the International Preliminary Examination Report

Confidential Treatment

Article 38; Rule 94.2

3.26 Until the international preliminary examination report has been established it remains confidential. Neither the International Bureau nor the International Preliminary Examining Authority may therefore allow access to the file of the international preliminary examination unless requested or authorized by the applicant. The International Preliminary Examining Authority should provide documents to any elected Office which so requests once the international preliminary examination report has been established. Subject to the reimbursement of cost, authorized copies of the documents concerned may be provided to a third party at the request of the applicant or any person authorized by the applicant.

Making Available of the International Preliminary Examination Report

Rule 94.1(c)

3.27 Once the report has been transmitted to the elected Offices by the International Bureau, 30 months from the priority date, the International Bureau will make the report available to the public on behalf of those elected Offices who have notified their wish for the International Bureau to supply this service, together with any translation and observations made by the applicant on the translation.

Transmission of the International Preliminary Examination Report to Elected Offices

Rules 73.2, 93bis.1

3.28 The International Bureau transmits the international preliminary examination report to the elected Offices after 30 months from the priority date, or earlier if the applicant makes a request for early national processing of the international application under Article 40(2). The transmittal by the International Bureau to any elected Office is effected only upon request by the Office concerned and at the time specified by that Office.

Translation of International Preliminary Examination Report

Rule 72

3.29 Where the international preliminary examination report is established in a language other than English, the International Bureau translates the report into English and transmits the translation to elected Offices who have requested such translations and also to the applicant. The applicant is entitled to make written observations on the correctness of the translation and sends copies of these observations to the International Bureau and to each of the interested elected Offices.

Further Responsibilities of the International Preliminary Examining Authority

Article 36(4); Rule 71.2

3.30 At any time within seven years of the international filing date of the international application, either the applicant or any elected Office is entitled to request copies of any documents cited in the international preliminary examination report which were not cited in the international search report to be sent to them by the International Preliminary Examining Authority, subject, if required by the Authority, to the payment of costs for preparing and mailing the copies (the applicant may be sent copies of such citations automatically with the international preliminary examination report).

PART II THE INTERNATIONAL APPLICATION

Chapter 4 Content of the International Application (Other Than the Claims)

General

Article 3(2)

- 4.01 The contents of the international application are set out in Article 3(2). The application must contain:
 - (i) a request (see the PCT Receiving Office Guidelines);
 - (ii) a description (see paragraphs 4.02 to 4.27);
 - (iii) one or more claims (see Chapter 5);
 - (iv) one or more drawings (where required; see paragraph 4.28); and
 - (v) an abstract (see Chapter 16).

This chapter discusses above items (ii) and (iv) insofar as they are the concern of the International Searching Authority and International Preliminary Examining Authority.

Description

Article 5

- 4.02 The international application must "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." The meaning of "person skilled in the art" is discussed in paragraph 13.11. This requirement of disclosure should be met by the description with the aid of drawings, if any. The provisions relating to the content of the description are set out in Rule 5. The purposes of these provisions are:
- (i) to ensure that the international application contains all the technical information required to enable a skilled person to put the invention into practice; and
- (ii) to enable the reader to understand the contribution to the art which the inventor has made.

Rule 5.1

4.03 The description should start with the same title that appears in the request (Form PCT/RO/101). The description should contain subheadings corresponding to those contained in Section 204 ("Technical Field", "Background Art", "Disclosure of Invention", "Brief Description of Drawings", "Best Mode(s) for Carrying Out the Invention", "Industrial Applicability" and, where appropriate, "Sequence Listing" and "Sequence Listing Free Text"). The use of such subheadings is strongly recommended in order to provide uniformity in publication and to facilitate access to the information contained in the international application. Some of the recommended subheadings are discussed in the following paragraphs.

Technical Field

Rule 5.1(a)(i)

4.04 The application should specify the technical field to which it relates.

Background Art

Rules 51(a)(ii), 6.3(b)(i)

4.05 The description should also mention any background art of which the applicant is aware, and which can be regarded as useful for understanding the invention and its relationship to the prior art; identification of documents reflecting such art, especially patent

specifications, should preferably be included. For further guidance concerning the statement of prior art-of references, see the appendix to this chapter. This applies in particular to the background art corresponding to those technical features of the invention which are necessary for the definition of the claimed subject matter but which, in combination, are part of the prior art (see Rule 6.3(b)(i) and paragraph 5.05).

Disclosure of Invention

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

- 4.06 The invention as claimed should be disclosed in such a way that the technical problem, or problems, with which it deals can be appreciated and the solution can be understood. To meet this requirement, only such details should be included as are necessary for elucidating the invention. Where the invention lies in realizing what the problem is (see Chapter 13), this should be apparent, and, where the means of solving the problem (once realized) are obvious, the details given of its solution may, in practice, be minimal.
- 4.07 When there is doubt, however, as to whether certain details are necessary, the examiner should not require their excision. It is not necessary, moreover, that the invention be presented explicitly in problem and solution form. Any advantageous effects which the applicant considers the invention to have in relation to the prior art should be stated, but this must not be done in such a way as to disparage any particular prior product or process. The prior art nor the applicant's invention cannot be referred to in a manner likely to mislead. This might be done, for example, by an ambiguous presentation which gives the impression that the prior art had solved less of the problem than was actually the case. Fair comment as referred to in paragraph 4.30 is permitted. Regarding amendment to, or addition of, a statement of problem, see paragraph 20.18.

Brief Description of Drawings

- 4.08 If drawings are included they should first be briefly described, in a manner such as: "Figure 1 is a plan view of the transformer housing; Figure 2 is a side elevation of the housing; Figure 3 is an end elevation looking in the direction of the arrow 'X' of Figure 2; Figure 4 is a cross-section taken through AA of Figure 1." When it is necessary to refer in the description to elements of the drawings, the name of the element should be referred to as well as its number, that is, the reference should not be in the form "3 is connected to 5 via 4" but "resistor 3 is connected to capacitor 5 via switch 4."
- 4.09 The description and drawings should be consistent with one another, especially in the matter of reference numbers and other signs (see paragraph 4.28). However, where, as a result of amendments to the description, whole passages are deleted, it may be tedious to delete all superfluous references from the drawings and in such a case the examiner need not pursue too rigorously the consistent use of reference signs as between the description and the drawings. The reverse situation should not occur, that is, all reference numbers or signs used in the description or claims should also appear on the drawings.

Best Mode for Carrying Out the Invention

Rule 5.1(a)(v)

4.10 The international application should set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this should be done in terms of examples, where appropriate, and with reference to the drawings, if any. The applicant need not point out which of their embodiments or examples they is considered to be the best mode. Determining compliance with the best mode requirement requires a two-prong inquiry. First, it must be determined whether, at the time the application was filed, the applicant contemplated a best mode for practicing the invention. This is a subjective inquiry which focuses on the applicant's state of mind at the time of filing. Second, if the inventor did, in fact, contemplate a best mode, it must be determined whether the written description disclosed the best mode such that a person skilled in the art could practice it. This is an

objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. The examiner should assume that the best mode is disclosed in the application, unless evidence is presented that is inconsistent with that assumption. It is therefore extremely rare that an objection based upon a lack of best mode would be made in an international application. There currently are diverging practices among the International Authorities and designated States with respect to the requirement for the application to set forth the best mode. Where the national law of a designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated has no effect in that State.

Structure and Function

4.11 In order that the requirements of Article 5 and of Rule 5.1(a)(iii) and (v) may be fully satisfied, it is necessary that the invention be described not only in terms of its structure but also in terms of its function, unless the functions of the various parts are immediately apparent. Indeed, in some technical fields (for example, computers), a clear description of function may be much more appropriate than an over-detailed description of structure.

Sufficiency

- 4.12 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 5.43 to 5.53). 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 20.03 and 20.10 *et seq.*). 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 5.54 to 5.58).
- 4.13 Occasionally international applications are filed in which there is a fundamental insufficiency in the invention in the sense that it cannot be carried out by a person skilled in the art; there is then a failure to satisfy the requirements of Article 5 which is essentially irreparable. Two instances thereof deserve special mention:
- (a) The first is where the successful performance of the invention is dependent on chance. That is to say, a person skilled in the art, in following the instructions for carrying out the invention, finds either that the alleged results of the invention are not reproducible or that success in obtaining these results is achieved in a totally unreliable way. An example where this may arise is a microbiological process involving mutations. Such a case should be distinguished from one where repeated success is assured even though accompanied by a proportion of failures as can arise, for example, in the manufacture of small magnetic cores or electronic components; in this latter case, provided the satisfactory parts can be readily sorted by a nondestructive testing procedure, no objection necessarily arises under Article 5.
- (b) The second instance is where successful performance of the invention is inherently impossible because it would be contrary to well-established physical laws. This applies, for example, to a perpetual motion machine (see paragraph 4.06).

Industrial Applicability

Article 33(1), and (4); Rule 5.1(a)(vi)

4.14 Refer to chapter 14 for discussion of the industrial applicability of the invention.

Nucleotide and/or Amino Acid Sequence Listings

Rules 5.2, 13ter.1(a), (c) and (e); Sections 208, 801; Al Annex C

4.15 Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences, the description should contain a separate sequence listing part complying with the standard provided for in Annex C of the Administrative Instructions. The sequence listing may be in written form and computer readable form, both forms complying with the standard provided for in Annex C. Instead of in written form, the sequence listing may be filed on an electronic medium under the provisions of Section 801 of the Administrative Instructions, where the receiving Office in which the international application was filed accepts sequence listings filed on an electronic medium. The International Searching Authority carries out the international search on the basis of those forms of the listing. For handling of the nucleotide and/or amino acid sequence listings, refer to paragraphs 9.39, 15.12 and 15.13 (search stage) and paragraphs 18.17 and 18.18 (examination stage).

Deposit of Biological Material

Rule 13bis

- 4.16 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 biological material which cannot otherwise be described in the application to meet the sufficiency of disclosure requirements of Article 5, the deposit of such material is taken into consideration when determining whether those requirements have been met.
- 4.17 The deposit is considered part of the description to the extent that the requirements regarding sufficiency of disclosure under Article 5 cannot otherwise be complied with; thus the deposit would be taken into account in determining compliance with such requirements. Therefore, mere reference to the deposited material in an application may not be sufficient to replace the explicit disclosure of such material in the application in order to comply with the sufficiency of disclosure 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.
- 4.18 In accordance with paragraphs 4.16 and 4.17, a deposit of biological material is taken into consideration in determining whether the sufficiency of disclosure requirements of Article 5 has been met. Further, in some Authorities, a deposit of biological material is also taken into consideration in determining whether the support requirement of Article 6 has been met.

References to Deposited Microorganisms or Other Biological Material as Part of the Description

Rule 13bis.7

4.19 The national law of certain States requires that references to deposited microorganisms or other biological material furnished under Rule 13*bis*.3(a) be included in the description (see the PCT Applicant's Guide, Volume I/B, Annex L). Where such a State is designated and indications are presented on a separate sheet such as Form PCT/RO/134 (which may be prepared using the PCT-EASY-SAFE software), that sheet should be numbered as a sheet of the description, but this matter is not considered by the International Authority.

Requirements as to the Language of Sheets Containing References to Deposited Microorganisms or Other Biological Material

Articles 11(1)(ii), 14(4); Rules 29.3, 30

4.20 Sheets containing references to deposited microorganisms or other biological material must, if they are part of the description, be in the same language as that of the description. This is a requirement for being accorded an international filing date

(Article 11(1)(ii), see paragraph 41 of the *PCT Receiving Office Guidelines*). If the International Searching Authority discovers less than four months from the international filing date that, despite an international filing date having been accorded, these sheets are not in the same language as that of the description, it notifies the Receiving Office using Form PCT/ISA/209, indicating that it considers that the receiving Office should make a finding that the international application is to be considered withdrawn under Article 14(4). If the receiving Office does not make such a finding within four months of the international filing date, the international application cannot be so considered withdrawn and the deficiency is merely noted in the written opinion (see paragraph 17.48). The applicant may then file an appropriate correction or (if international preliminary examination is demanded) amendment.

General

Rule 5.1(b); Section 204

4.21 The manner and order of presentation of the various parts of the description should be that specified in Rule 5.I(a) and Section 204 (see paragraph 4.03), unless, "because of the nature of the invention, a different manner or a different order would result in a better understanding and a more economic presentation." Since the responsibility for a clear and complete description of the invention lies with the applicant, the examiner should exercise his discretion as to whether to object to the presentation. Some departure from the requirements of Rule 5.I(a) is acceptable, provided the description is clear and orderly and all the requisite information is present. For example, the requirements of Rule 5.I(a)(iii) (see paragraph 4.06) may be waived where the invention is based on a fortuitous discovery, the practical application of which is recognized as being useful, or where the invention breaks entirely new ground. Also certain technically simple inventions may be fully comprehensible with the minimum of description and but slight reference to prior art.

Rule 10.2

- 4.22 The description should be clear and straightforward with avoidance of unnecessary technical jargon. In general, only such technical terms, signs and symbols should be used as are generally accepted in the art. Little known or specially formulated technical terms may be allowed, provided that they are adequately defined and that there is no generally recognized equivalent. This discretion may be extended to foreign terms when there is no equivalent in the language of the international application. Terms already having an established meaning must not be used to mean something different as this is likely to cause confusion. There may be circumstances where a term may legitimately be borrowed from an analogous art. Terminology and signs should be consistent throughout the international application.
- 4.23 In the particular case of inventions in the computer field, program listings in programming languages cannot be relied on as the sole disclosure of the invention. The description, as in other technical fields, should be written substantially in normal language, possibly accompanied by flow diagrams or other aids to understanding, so that the invention may be understood by those skilled in the art. Short excerpts from programs written in commonly used programming languages can be accepted if they serve to illustrate an embodiment of the invention.

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

When the properties of a material are referred to, the relevant units should be specified if quantitative considerations are involved. If this is done by reference to a published standard (for example, a standard of sieve sizes), and such standard is referred to by a set of initials or similar abbreviation, it should be adequately identified in the description. The metric system of units of weight and measures should be used or, if another system is used, the units should additionally be expressed in the metric system. Similarly, temperature should be expressed in degrees Celsius or also expressed in degrees Celsius if first expressed in a different manner. Other physical values (that is, other than those having units directly derivable from length, mass, time and temperature) should be expressed in the units recognized in international practice; for example, for electric units the MKSA (Meter,

Kilogram, Second, Ampere) or SI (Système International) systems should be used. Chemical and mathematical symbols, atomic weights and molecular formulae should be those in general use, and technical terms, signs and symbols should be those "generally accepted in the art." In particular, if there are any agreed international standards in the art in question, these should be adopted wherever practicable.

- 4.25 The use of proper names or similar words to refer to materials or articles is undesirable insofar as such words merely denote origin or where they relate to a range of different products. If such a word is used, then in order to satisfy the requirements of Article 5, the product should normally be sufficiently identified, without reliance upon the word, to enable the invention to be carried out by a person skilled in the art. However, where such words have become internationally accepted as standard descriptive terms and have acquired a precise meaning (for example, "Bowden" cable, "Bellville" washer), they may be allowed without further identification of the product to which they relate.
- References in international applications to other documents may relate either to the background art or to a part of the disclosure of the invention. Where the reference relates to the background art, it may be in the application as originally filed or introduced at a later date (see paragraph 20.18). Where the reference relates directly to the disclosure of the invention (for example, details of one of the components of a claimed apparatus) then, if it is to be taken into account in respect of Article 5, it must be in the application as originally filed and clearly identify the document referred to in such a manner that the document can be easily retrieved. If matter in the document referred to is essential to satisfy the requirements of Article 5, this matter should be incorporated into the description, because the patent specification should, regarding the essential features of the invention, be self-contained, that is, capable of being understood without reference to any other document.
- 4.27 A reference in the description to an unpublished, previously filed application (that is, not published before the international filing date) should not be regarded as being part of the disclosure, unless the application referred to is made available to the public on or before the publication date of the international application. The reference to such an application made available to the public on or before the publication date of the international application may be replaced by the actual text referred to and may be taken into account by the examiner. Similarly, references to textbooks and periodicals are allowable under the same conditions if it can be proved that the content thereof was fixed prior to the international filing date. In the case of any document made available to the public later than the publication date of the international application or not to be published at all (for example, an application withdrawn before publication), the examiner should not take into account the reference to that document for the purposes of international preliminary examination. It should be noted, however, that this practice relates only to the international phase and does not preclude any designated or elected Office applying the relevant national law as far as it relates to the contents of the disclosure of the international application as filed.

Drawings

Rule 11

4.28 The formal requirements relating to drawings are set down in Rules 11.10 to 11.13. The only question likely to cause difficulty is whether the text matter included on the drawings is absolutely indispensable. In the case of circuit diagrams, block schematics and flow sheets, identifying catchwords for functional integers of complex system (for example, "magnetic core store," "speed integrator") may be regarded as indispensable from a practical point of view if they are necessary to enable a diagram to be interpreted rapidly and clearly. However, such items can often be identified by a single numeral or letter which is then explained in the description.

Expressions, Etc., Not to Be Used

Rule 9.1(i), and (ii)

4.29 There are four categories of expressions which should not be contained in an international application. These categories are specified in Rule 9.1. Examples of the kind of matter coming within the first and second categories (contrary to morality or public order ("ordre public")) are: incitement to riot or to acts of disorder; incitement to criminal acts; racial, religious or similar discriminatory propaganda; and grossly obscene matter. The purpose of Rule 9 is to prohibit the kind of matter likely to induce riot or public disorder, or lead to criminal or other generally offensive behavior. This Rule is likely to be invoked by the examiner only in rare cases.

Rule 9.1(iii)

4.30 It is necessary to discriminate in the third category (disparaging statements) between libelous or similarly disparaging statements, which are not allowed, and fair comment, for example, in relation to obvious or generally recognized disadvantages, or disadvantages stated to have been found by the applicant, which, if relevant, is permitted.

Rule 9.1(iv)

- 4.31 The fourth category is irrelevant matter. It should be noted, however, that such matter is specifically prohibited under the Rule only if it is "obviously irrelevant or unnecessary," for instance, if it has no bearing on the subject matter of the invention or its background of relevant prior art (see also paragraph A4.05[2] in the appendix to this chapter). The matter to be removed may already be obviously irrelevant or unnecessary in the original description. It may, however, be matter which has become obviously irrelevant or unnecessary only in the course of the examination proceedings, for example, owing to a limitation of the claims of the patent to one of the originally several alternatives.
- 4.32 Generally, the receiving Office (see the *PCT Receiving Office Guidelines*) or the International Searching Authority (see paragraph 15.35) will deal with matter falling under Rule 9.1. If any such matter has not been recognized at one of these earlier stages, the International Preliminary Examining Authority may also invite the applicant to remove such matter. The applicant should be informed of the category applied under which the prohibited matter is to be removed.

Appendix to Chapter 4

Background Art

A4.05 The International Preliminary Examining Authorities have divergent practices concerning whether it is appropriate to invite the applicant to introduce references to the prior art into the international application. The guidelines below may be relied upon by the Authorities as appropriate.

A4.05[1] The insertion into the statement of prior art of references to documents identified subsequently, for example by the search report, may be appropriate, provided that the amendment would not go beyond the disclosure in the international application as filed. For instance, while the originally filed description of prior art may give the impression that the inventor has developed the invention from a certain point, the cited documents may show that certain stages in, or aspects of, these alleged developments were already known. The examiner may invite the inclusion of a reference to these documents and a brief summary of the relevant contents. Care should be taken that any such inclusion does not contravene Article 34(2)(b) (see paragraphs 20.10 to 20.19).

A4.05[2] Since the reader is presumed to have the general background and technical knowledge appropriate to the art, and it is not in any case permitted to make amendments which go beyond the disclosure as filed, the examiner should not invite the applicant to insert anything in the nature of a treatise or research report or explanatory matter which is obtainable from textbooks or is otherwise well known. Likewise, the examiner should not invite the applicant to provide a detailed description of the content of cited prior documents.

It is sufficient that the reason for the inclusion of the reference is indicated, unless, in a particular case, a more detailed description is necessary for a full understanding of the claimed invention. Lists of several reference documents relating to the same feature or aspect of the prior art are not required; only the most appropriate ones need to be referred to. On the other hand, the examiner should not invite the applicant to excise-delete any such unnecessary matter, except when it is very extensive.

Chapter 5 Claims

General

Article 3(2)

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

Article 6

- 5.02 The claims must:
 - (i) "define the matter for which protection is sought;"
 - (ii) "be clear and concise;" and
 - (iii) "be fully supported by the description."
- 5.03 This chapter sets out the appropriate form and content of the claims, together with how they should be interpreted for the purposes of assessing the novelty and inventive step of the inventions which they define, and searching for prior art which may be relevant to making that determination.

Form and Content of Claims

Rule 6.3(a)

This means that claims should not contain any statements relating, for example, to commercial advantages or other non-technical matters, but statements of purpose should be allowed if they assist in defining the invention. It is not necessary that every feature should be expressed in terms of a structural limitation. Since it is a matter for national law, the examiner should normally not object to the inclusion of functional limitations in a claim provided that a person skilled in the art would have no difficulty in providing some means of performing this function without exercising inventive skill or that such means are fully disclosed in the application concerned. A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person skilled in the art in the context in which it is used. Claims to the use of the invention in the sense of the technical application thereof are permissible. See paragraph 5.21.

Rule 6.3(b)(ii), and (c); Section 205

Rule 6.3(b) defines the two-part form which a claim should take "whenever appropriate." The first part should contain a statement indicating the designation of the subject matter of the invention, that is, the general technical class of apparatus, process, etc., to which the claimed invention relates, followed by a statement of those technical features "which are necessary for the definition of the claimed subject matter but which, in combination, are part of the prior art." It is clear from this wording that it is necessary only to refer to those prior art features which are relevant to the invention. For example, if the invention relates to a photographic camera but the claimed inventive step relates entirely to the shutter, it would be sufficient for the first part of the claim to read: "A photographic camera including a focal plane shutter having..." (here recite the known combination of features which is utilized) and there is no need to refer also to the other known features of a camera such as the lens and viewfinder. The second part or "characterizing portion" should state the technical features which, in combination with the features stated under the first part (Rule 6.3(b)(i)), it is desired to protect, that is, the features which the invention adds to the prior art. If the search results, or any additional documents considered to be relevant in accordance with Article 33(6), reveal that any feature in the second part of the claim was, in fact, already known in combination with all the features in the first part of the claim and in that combination have the same effect as they have in the full combination according to the claimed invention, the examiner may invite the applicant to transfer such feature or features to the first part. Where, however, a claim relates to a novel combination, and where the division of the features of the claim between the prior art part and the characterizing part

could be made in more than one way without inaccuracy and if the division of the features chosen by the applicant is not incorrect, the examiner should take no action. If the examiner, in the first written opinion, invites the applicant to adopt a different division but the applicant does not follow the invitation, the examiner should not pursue the matter further since the manner of claiming is a matter for national laws of designated or elected States.

- 5.06 The applicant may be invited to follow the above two-part formulation where, for example, it is clear that the applicant's invention resides in a distinct improvement in an old combination of parts or steps. However, as is indicated by Rule 6, this form need only be used in appropriate cases. The nature of the invention may be such that this form of claim is unsuitable, for example, because it would give a distorted or misleading picture of the invention or the prior art. Examples of the kind of invention which may require a different presentation are:
- (i) the combination of known elements or steps of equal status, the inventive step lying solely in the combination;
- (ii) the modification of, as distinct from addition to, a known chemical process, for example, by omitting one substance or substituting one substance for another; and
- (iii) a complex system of functionally interrelated parts, the inventive step concerning changes in several of these parts or in their interrelationships.
- 5.07 In examples (i) and (ii), the two-part form of claim according to Rule 6.3(b) may be artificial and inappropriate, whereas, in example (iii), it might lead to an inordinately lengthy and involved claim. Another example in which the two-part form of claim provided for in Rule 6.3(b) may sometimes be inappropriate is where the claimed invention is a new chemical compound or group of compounds that does not fall within a known class. It is also likely that other cases will arise in which it will be appropriate to formulate the claim in a different form.
- 5.08 When determining whether or not to invite the applicant to put a claim in the two-part form provided by Rule 6.3(b), it is important to assess whether this form is "appropriate." In this respect, it should be borne in mind that the purpose of the two-part form of claim is to allow the reader to see clearly which features necessary for the definition of the claimed subject matter are, in combination, part of the prior art. If this is sufficiently clear from the indication of prior art provided in the description, to meet the requirement of Rule 5.1(a)(ii), it is appropriate to present the claim in a form other than the two-part form provided by Rule 6.3(b).

Rule 11.10(a), (b), and (c)

5.09 The claims, as well as the description, "may contain chemical or mathematical formulae" but not drawings. "Any claim may contain tables" but "only if the subject matter of the claim makes the use of tables desirable." In view of the use of the word "desirable," the examiner should not object to the use of tables in claims where this form is convenient.

Rule 6.2(a)

5.10 The claims must not, in respect of the technical features of the invention, rely on references to the description or drawings "except where absolutely necessary." In particular, they must not normally rely on references such as: "as described in part ... of the description" or "as illustrated in Figure 2 of the drawings." The emphatic wording of the excepting clause should be noted. Thus, the applicant should be invited to show that it is "absolutely necessary" to rely on reference to the description or drawings in appropriate cases. An example of an exception would be that in which the invention as claimed involved some peculiar shape illustrated in the drawings but which could not be readily defined either in words or by a simple mathematical formula. Another special case is that in which the invention relates to chemical products whose features can be defined only by means of graphs or diagrams.

Rule 6.2(b)

5.11 If there are drawings and the technical features of the claims would be rendered more intelligible by relating those features to the corresponding features of the drawings, this should preferably be done by placing the appropriate reference signs in parentheses after the features in the claims. This should be done in both parts of claims having the preferred form specified in Rule 6.3(b). These reference signs are not, however, to be construed as limiting the scope of a claim, but merely as aids to an easier understanding of the defined subject matter.

Kinds of Claim

Categories

Rule 13: Section 206: Al Annex B

- There are two basic kinds of claim, viz., claims to a physical entity (product, apparatus) and claims to an activity (process, use). The first basic kind of claim ("product claim") includes a substance or composition (for example, chemical compound or a mixture of compounds) as well as any physical entity (for example, object, article, apparatus, machine, or system of cooperating apparatus) which is produced by a person's technical skill. Examples are "steering mechanism incorporating an automatic feedback circuit...;" "a woven garment comprising ...;" "an insecticide consisting of X, Y, Z;" or "a communications system comprising a plurality of transmitting and receiving stations." The second basic kind of claim ("process claim") is applicable to all kinds of activities in which the use of some material product for effecting the process is implied; the activity may be exercised upon material products, upon energy, upon other processes (as in control processes) or upon living things (see, however, paragraphs 9.04 to 9.15 which relate to subjects that may be excluded from international search or preliminary examination).
- 5.13 It should be noted that claims which are worded differently may, in reality, fall within the same category and have effectively the same scope. For example, a claim referring to a "system" and a claim referring to "apparatus" may both be in the "apparatus" category. It should be further noted that it is permitted to include in the same international application claims of the said different categories provided that they comply with the requirement of Rule 13.1 (see Chapter 10). The examiner should bear in mind that the presence of such different claims may assist an applicant in later obtaining full protection for the invention in all the designated/elected States since infringement of a patent is dealt with by national law. Consequently, while the examiner should draw attention to an unnecessary proliferation of independent claims (see paragraph 5.42), he should not adopt an overacademic or rigid approach to the presence of a number of claims which are differently worded but apparently of similar effect.
- 5.14 Rule 13.3 states that "the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim." This means that while the examiner should take exception to an unnecessary proliferation of independent claims, the examiner should not take exception to two or more independent claims in the same category, provided that there is a unifying inventive concept and that the claims as a whole satisfy the requirement of Article 6 that they should be "concise" (see paragraph 5.42). In applying this principle, the examiner should have regard to the remarks made in paragraph 5.13 concerning claims of apparently similar scope. However there are other circumstances where it may not be appropriate to cover the subject matter of an invention by a single independent claim in a particular category, for example, (1) where the invention relates to an improvement in two separate but interrelated articles which may be sold separately, such as an electric plug and socket or transmitter and receiver, (2) where an invention is concerned with electrical bridge-rectifier circuits, it might be necessary to include separate independent claims to a single-phase and to poly-phase arrangements incorporating such circuits since the number of circuits needed per phase is different in the

two arrangements, (3) where the invention resides in a group of new chemical compounds and there are a number of processes for the manufacture of such compounds.

Independent and Dependent Claims

Rule 13.4

All international applications will contain one or more independent main claims directed to the essential features of the invention. Any such claim may be followed by one or more claims concerning specific forms of that invention. It is evident that any claim relating to a specific form must effectively include also the essential features of the invention, and hence must include all the features of at least one independent claim. The specific forms should be construed broadly as meaning any more specific definition or specifically different embodiments of the invention than that set out in the main claim or claims. It should be noted that, subject to Rule 13.1, it is permitted to include a reasonable number of dependent claims claiming specific forms of the claimed invention in the independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.

Rules 6.4(a) and (b), 66.2(a)

5.16 Any dependent claim must include a reference to the claim from which it depends, and must be construed as including all the limitations contained in the claim to which it refers. A multiple dependent claim includes all the limitations contained in the particular claim in relation to which it is considered. See the appendix to this chapter and paragraph 9.41 for further guidance with respect to multiple dependent claims.

Rule 6.4(c)

- 5.17 All dependent claims, however referred back, should be grouped together to the extent and in the most practical way possible. The arrangement must therefore be one which enables the association of related claims to be readily determined and their meaning in association to be readily construed. The examiner should invite the applicant to submit a suitable amendment if the arrangement of claims is such that it creates obscurity in the definition of the subject matter to be protected.
- 5.18 A claim, whether independent or dependent, can contain alternatives, provided those alternatives are of a similar nature and can fairly be substituted one for another, and provided also that the number and presentation of alternatives in a single claim does not make the claim obscure or difficult to construe (see also paragraphs 10.09 and 10.17).
- A claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, in a situation like a plug and socket example, a claim to the one part referring to the other cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...," is not a dependent claim as it does not expressly contain the limitations of the earlier claim from which it depends, rather it only has a functional relationship to that earlier claim.

Interpretation of Claims

Article 6

Claims should be interpreted the same way for both search and examination purposes. Each claim should be read giving the words the ordinary meaning and scope which would be attributed to them by a person skilled in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise. See the appendix to this chapter for further guidance with regard to the interpretation of claims.

"Use" Claims

5.21 A claim to a substance or composition for a particular use should generally be construed as meaning a substance or composition which is in fact suitable for the stated use;

a known product which *prima facie* is the same as the substance or composition defined in the claim, but which is in a form which would render it unsuitable for the stated use, would not deprive the claim of novelty, but if the known product is in a form in which it is in fact suitable for the stated use, though it has never been described for that use, it would deprive the claim of novelty. For example, a claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods that is presented in a form such as: "substance or composition X" followed by the indication of the use, for instance "... for use as a medicament", "... as an antibacterial agent" or "... for curing disease Y" will be regarded as restricted to the substance or composition when presented or packaged for the use. See also paragraph 5.22. See the appendix to this chapter for further guidance with respect to use claims, and for an explanation of when an Authority may regard a "use" claim as equivalent to a "process" claim.

Preamble

- 5.22 The effect of the preamble on the evaluation of the elements of a claim for search and examination purposes should be determined on a case by case basis in light of the facts in each case. During search and examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, a difference in process steps) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. In two-part claims as defined in Rule 6.3(b), the preamble is regarded as a limitation on the scope of the claim.
- If a claim commences with such words as "Apparatus for carrying out the process, 5.23 etc....." this must be construed as meaning merely apparatus suitable for carrying out the process. An apparatus which otherwise possesses all of the features specified in the claim, but which would be unsuitable for the stated purpose or which would require modification to enable it to be so used, should not normally be considered as coming within the scope of the claim. For example, a claim recites a machine for cutting meat comprising apparatus limitations. The claim language "machine for cutting meat" sets forth only the function of the apparatus (that is, for cutting meat) without any positive structural limitations. Such language would not be given any weight in assessing novelty and inventive step as long as the prior art cutting machine was capable of cutting meat. In this case, one should treat the words "for cutting meat" merely as limitation to a machine adapted to cut meat. Thus, one would look to the prior art to see whether the cutting machine would be inherently capable of cutting the meat, whether or not the prior art description specified what material is cut by the machine. Similar considerations apply to a claim for a product for a particular use. For example, if a claim refers to "mold for molten steel," this implies certain limitations for the mold. Therefore, a plastic ice cube tray with a melting point much lower than that of steel would not come within the claim. Similarly, a claim to a substance or composition for a particular use should be construed as meaning a substance or composition which is in fact suitable for the stated use; a known product which is per se the same as the substance or composition defined in the claim, but which is in a form which would render it unsuitable for the stated use, would not deprive the claim of novelty.

Open and Closed Claims

- In evaluating novelty or inventive step, the examiner should consider which type of the transition phrase, such as "consisting of," "comprising," "characterized by," or "consisting essentially of" is used in the claims. The subject matter to be searched depends on the type of transition phrase used.
- (a) Where a claim is drafted using a "closed" type of transition phrase, the claim cannot be construed as including products or processes that include structural elements or process steps other than those set forth in the claim. For example, if a claim recites "a product consisting only of A, B and C," it cannot be construed as including, and is novel over, prior art that discloses a product having A, B, C and D, or any other additional feature or

elements. The phrase "consisting of" may be interpreted by some Authorities as a "closed" type of transition phrase, however, other Authorities treat such language as equivalent to "consisting essentially of" as noted in (c) below.

- (b) Where a claim is drafted using an "open" type of transition phrase, it can be construed as including products or processes that include non-recited components or process steps, respectively. For example, if a claim recites "a product comprising A, B and C," it can be construed as including, and lacks novelty over, prior art that discloses a product having A, B, C and D, as well as any additional feature or element.
- (c) Where a claim is drafted using "consisting essentially of" as the transition phrase, the claim occupies a middle ground between closed claims that are written in a closed format and fully open claims. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. For the purposes of search and examination, absent a clear indication in the description or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to open (for example, "comprising") language.

Means-Plus-Function Claims

Where a limitation in the claim defines a means or a step in terms of its function or characteristics without specifying the structure or material or act in support thereof, such a limitation should be construed as defining any structure or material or act which is capable of performing the defined function or which has the defined characteristics, unless the means are further specified in the claim. If the means are further specified, the claim would be interpreted to include those further specified limitations. For example, if a claim recites valve means for restricting the flow of fluid, it would be interpreted by the examiner to include the further specified limitation of a valve means rather than any means for restricting flow of fluid. As another example, a claim aimed at "a building material incorporating a layer which insulates heat" should be interpreted as a building material incorporating any "product" that is "a layer which insulates heat." It should be noted, however, that the issues of whether such means-plus-function claims are clear and concise or not and whether the disclosure of the claimed invention is sufficient for a person skilled in the art or not should be determined separately.

"Product-by-Process" Claims

- 5.26 Where a claim defines a product in terms of the process by which the product is made, the claim as a whole is directed to a product. Such a claim lacks novelty if a prior art product, even if made by an undisclosed process, appears to be inherently the same as, or indistinguishable from, the claimed invention. See the appendix to this chapter for more guidance with respect to product by process claims.
- 5.27 Where a product can only be defined by the process steps by which the product is made, or where the manufacturing process would be expected to impart distinctive characteristics on the final product, the examiner would consider the process steps in determining the subject of the search and assessing patentability over the prior art. For example, a claim recites "a two-layer structured panel which is made by welding together an iron sub-panel and a nickel sub-panel." In this case, the process of "welding" would be considered by the examiner in determining the subject of the search and in assessing patentability over the prior art since the process of welding produces physical properties in the end product which are different from those produced by processes other than welding; that is, the product can only be defined by the process step. Novelty of the claim is not brought into question unless an identical two-layer structural panel made by means of welding is discovered in the prior art.

Product and Apparatus Limitations in Process Claims

5.28 Product and apparatus limitations that appear in process claims must be taken into account for search and examination purposes. See paragraph 5.22 for the effect of the preamble on claim interpretation.

Inconsistency Between Claims and Description

- 5.29 Where there is any serious inconsistency between claims and description, amendments to remove this should be invited from the applicant. For example, the description may state, or may imply, that a certain technical feature not mentioned in the claims is essential to the performance of the invention. In such a case, the examiner should invite amendment of the claims to include this feature. However, if the applicant can show convincingly by way of response that it would be clear to a person skilled in the art that the description was incorrect in suggesting that the feature in question was essential, amendment of the description should be invited instead. Another form of inconsistency is that in which the description and drawings include one or more embodiments of the invention which appear to fall outside the subject matter covered by the claims (for example, the claims all specify an electric circuit employing electronic tubes and one of the embodiments employs semiconductors as an alternative). Here again the applicant should be invited to amend the claim or the description and drawings to remove the inconsistency and thus avoid any possible uncertainty which could arise later as to the meaning of the claims. However, inconsistencies which do not cause doubt as to the meaning of the claims may be overlooked.
- 5.30 General statements in the description which imply that the extent of protection may be expanded in some vague and not precisely defined way should be objected to as not complying with Article 6. In particular, objection should be raised to any statement which refers to the extent of protection being expanded to cover the "spirit" of the invention. Where the claims are directed to a combination of features only, any statement in the description which seems to imply that protection is nevertheless sought not only for the combination as a whole but also for individual features or sub-combinations thereof should be objected to.

Clarity

Article 6

- 5.31 The requirement that the claims should be clear applies to individual claims and also to the claims as a whole. The clarity of the claims is of the utmost importance for the purposes of formulating an opinion on the questions of whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable in view of their function in defining the matter for which protection is sought. Therefore the meaning of the terms of a claim should, as far as possible, be clear for the person skilled in the art from the wording of the claim alone (see also paragraph 5.20).
- 5.32 Each claim must set forth the scope of the invention sought to be protected with a reasonable degree of clarity. Clarity of claim language must be analyzed in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by the person skilled in the art at the time the invention was made. If a person skilled in the art can determine the boundaries of the claimed invention with a reasonable degree of certainty, the claim complies with the requirement for clarity. Breadth of a claim is not to be equated with lack of clarity. If the scope of the subject matter embraced by the claims is clear, and if the applicant has not otherwise indicated that he intends the invention to be of a scope different from that defined in the claims, then the claims comply with the requirement for clarity.
- 5.33 An independent claim should clearly specify all of the essential features needed to define the invention except insofar as such features are implied by the generic terms used—if or example, a claim to a "bicycle" does not need to mention the presence of wheels. If a claim is to a process for producing the product of the invention, then the process as claimed

should be one which, when carried out in a manner which would seem reasonable to a person skilled in the art, necessarily has as its end result that particular product; otherwise, there is an internal inconsistency and therefore lack of clarity in the claim. In the case of a product claim, if the product is of a well-known kind and the invention lies in modifying it in a certain respect, it is sufficient if the claim clearly identifies the product and specifies what is modified and in what way. Similar considerations apply to claims for an apparatus.

Clarity of Relative Terms

- A claim that includes vague or equivocal forms of wording which leave the reader in doubt as to the scope of a feature should be objected to for lack of clarity. A claim should not use a relative or similar term such as "thin", "wide" or "strong" unless the term has a well-recognized meaning in the particular art, for example "high-frequency" in relation to an amplifier, and this is the meaning intended. If a term of degree appears in a claim, the examiner should determine whether one skilled in the art would be apprised of the meaning of the term either by a disclosure of a standard for measuring that degree in the description or in view of the prior art and state of the art. It may be appropriate to invite the applicant to either define or excise the term if he could do so without extending the subject matter beyond the content of the application as filed in contravention of Article 19(2) or 34(2)(b). An applicant cannot rely on an unclear term to distinguish the claimed invention from the prior art.
- 5.35 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 where 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 5.46), for example, 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 smouldering 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 without being objected to for lack of clarity, provided that the description includes adequate directions to enable the reader to determine the required dimensions by routine test procedures.
- Where the invention relates to a product, it may be defined in a claim in various ways, viz., by a chemical formula, as a product of a process or by its parameters. Definition of a product 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 recognized 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. Cases in which non-art recognized parameters are employed, or a non-accessible apparatus for measuring the parameter(s) is used, may be objectionable on grounds of lack of clarity. The examiner should be aware of the possibility that applicants may attempt to employ unusual parameters to disguise lack of novelty (see paragraph 12.04).
- 5.37 Where a claim for an apparatus or a product seeks to define the invention by reference to features of the use to which the apparatus or product is to be put, a lack of clarity can result. This is particularly the case where the claim not only defines the product itself but also specifies its relationship to a second product which is not part of the claimed invention (for example, a cylinder head for an engine, where the former is defined by features of where it is connected in the latter). Such a claim must either set forth a clear definition of the individual product being claimed by wording the claims appropriately (for example, by

substituting "connectable" for "connected"), or be directed to a combination of the first and second products (for example, "engine with a cylinder head" or "engine comprising a cylinder head"). It may also be permissible to define the dimensions and/or shape of a first product in an independent claim by general reference to the dimensions and/or corresponding shape of a second product that is not part of the claimed first product but is related to it through use (for example, in the case of a mounting bracket for a vehicle number-plate, where the bracket frame and fixing elements are defined in relation to the outer shape of the number-plate).

5.38 Particular attention is required whenever the word "about" or similar terms, such as "approximately," are used. Such a word may be applied, for example, to a particular value (for example, "about 200°C") or to a range (for example, "about X to about Y"). In each case, the examiner should exercise judgment as to whether the meaning is sufficiently clear in the context of the application read as a whole. Moreover, if such words as "about" prevent the invention from being unambiguously distinguished from the prior art, an objection should be raised as to lack of novelty or inventive step.

Clarity of Other Terms

- 5.39 Trademarks and similar expressions characterize the commercial origin of goods, rather than the properties of the goods (which may change from time to time) relevant to the invention. Therefore the examiner should invite the applicant to remove trademarks and similar expressions in claims, unless their use is unavoidable; they may be allowed exceptionally if they are generally recognized as having a precise meaning (see also paragraph 5.34).
- 5.40 Expressions like "preferably," "for example," "such as" or "more particularly" should be looked at carefully to ensure that they do not introduce ambiguity. The examiner should regard expressions of this kind as having no limiting effect on the scope of a claim; that is to say, the feature following any such expression should be regarded as entirely optional.
- Generally, the subject matter of a claim is defined by means of positive features. However, the extent of a claim may be limited by means of a "disclaimer," a "negative limitation," or an "exclusion;" in other words, an element clearly defined by technical features may be expressly excluded from the protection claimed, for example in order to meet the requirement of novelty. A claim may also include a negative limitation or language that defines subject matter that is not present in the claimed invention (for example, "wherein the composition is free of water"). There is nothing per se ambiguous or uncertain about a negative limitation. A negative limitation renders the claim unclear where it is an attempt to claim the invention by excluding what the applicant did not invent rather than clearly and concisely reciting what he did invent. A claim which recites the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, is considered to be clear where each recited limitation is clear. In addition, the negative limitation "incapable of forming a dye with said oxidized developing agent" is clear because the boundaries of the patent protection sought are clear. If alternative elements are positively recited in the description, they may be explicitly excluded in the claims. The mere absence of a positive recitation is not basis for exclusion.

Conciseness, Number of Claims

Rule 6.1(a)

5.42 The requirement that the claims should be concise refers to the claims in their entirety as well as to the individual claims. For example, undue repetition of words or an undue multiplicity of claims of a trivial nature could be considered as not complying with this requirement. See the appendix to this chapter for further guidance relating to determinations of "conciseness" of claims.

Support in Description

Article 6

- 5.43 The claims "shall be fully supported by the description." This means that there must be a basis in the description for the subject matter of every claim and that the scope of the claims must not be broader than is justified by the description and drawings.
- As a general rule, a claim is regarded as supported by the description unless, exceptionally, there are well-founded reasons for believing that the person skilled in the art would be unable, on the basis of the information given in the application as filed, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis. Support must, however, relate to the features of the claimed invention; vague statements or assertions having no technical or other relevant content provide no basis. The examiner should raise an objection of lack of support only if there are well-founded reasons. Where an objection is raised, the reasons, where possible, should be supported specifically by a published document.

Clear and Complete Disclosure of Claimed Invention

Article 5

- The subject matter of each claim must be 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." The disclosure of the claimed invention is considered sufficiently clear and complete if it provides information which is sufficient to allow the invention to be carried out by a person skilled in the art as of the international filing date, without undue experimentation.
- 5.46 The disclosure is aimed at a person skilled in the art (see paragraph 13.11). This person is considered, if necessary, to use the general knowledge which would be possessed by such a person to supplement the information contained in the application. The disclosure must be sufficient to carry out the invention on the basis of the knowledge of a person skilled in the art at the time of the international filling date, not at the time of the search and examination. Although a reasonable amount of trial and error is permissible, a person skilled in the art must, on the basis of the disclosure of the claimed invention and the general knowledge, be able to carry out the invention without "undue experimentation." This is applicable particularly in the field of unexplored technologies.
- 5.47 Factors to be considered in determining whether undue experimentation is needed to carry out the claimed invention include:
 - (i) the breadth of the claims;
 - (ii) the nature of the invention;
 - (iii) the general knowledge of a person skilled in the art;
 - (iv) the level of predictability in the art;
- (v) the amount of direction provided in the application, including references to prior art; and
- (vi) the amount of experimentation required to carry out the claimed invention on the basis of the disclosure.
- 5.48 The breadth of the claims is relevant to the determination of undue experimentation, since a person skilled in the art must be able to carry out the entire scope of the claimed invention. For example, the applicant is not entitled to claim everything within the scope of the invention; if the application only discloses how to carry out part of the claimed invention. However, even in unpredictable arts, it is not necessary to provide examples covering every possible variation within the scope of a claim. Representative examples together with an explanation of how these can be applied to the scope of the claim

as a whole will ordinarily be sufficient if a person skilled in the art could carry out the claimed invention without undue experimentation.

- 5.49 The subject matter to which the claimed invention pertains, is essential to determine the general knowledge of a person skilled in the art and the state of the art. For example, if the selection of the values for various parameters is a matter of routine for a person skilled in the art, such a selection may not be considered as requiring undue experimentation.
- 5.50 "The amount of direction provided in the application" refers to the information explicitly or implicitly contained in the description, claims and drawings, including working examples and references to other applications or documents. The more that is known in the prior art by a person skilled in the art about the nature of the invention and the more the art is predictable, the less information in the application itself is needed in order to carry out the claimed invention. For example, there is predictability in the art if a person skilled in the art can readily anticipate the effect of a feature of the claimed invention.
- 5.51 In addition to the time and expenses needed for carrying out the experimentation, the character of the experimentation, for example, whether it constitutes merely routine work or goes beyond such routine, should also be considered.

Sufficiency Commensurate with the Claims

- 5.52 Most claims are generalizations from one or more particular examples. The extent of generalization permissible is a matter which the examiner must judge in each particular case in the light of the relevant prior art. An appropriate claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the applicant of a just reward for the disclosure of the invention. Obvious modifications and uses of and equivalents to that which the applicant has described should not be questioned. In particular, if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the description, it is proper for the applicant to draft the claims accordingly.
- A claim in generic form, that is, relating to a whole class, for example, of materials or machines, may be acceptable even if of broad scope, if there is fair support in the description and there is no reason to suppose that the invention cannot be carried out through the whole of the field claimed. Where the information given appears insufficient to enable a person skilled in the art to extend the teaching of the description to parts of the field claimed but not explicitly described by using routine methods of experimentation or analysis, the examiner should invite the applicant to establish, by suitable response, that the invention can in fact be readily applied on the basis of the information given over the whole field claimed or, failing this, to restrict the claim to accord with the description. An example of this might be a claim to a specified method of treating "synthetic resin moulding" to obtain certain changes in physical characteristics. If all of the examples described related to thermoplastic resins, and the method was such as to appear inappropriate to thermosetting resins, then limitation of the claims to thermoplastic resins might be necessary to comply with the sufficiency requirement.

Relationship of Claims to Disclosure

- 5.54 The claimed invention must be fully supported by the description and drawings, thereby showing that the applicant only claims subject matter which he had recognized and described on the international filing date.
- 5.55 The claims are not consistent and not commensurate with the description and drawings if, after reading the application, the claimed invention is still not at the disposal of a person skilled in the art, because an essential element for the function or operation of the invention is missing from the claim. For example, consider a claim that relates to improved fuel oil compositions which have a given desired property. The description provides support for one way of obtaining fuel oils having this property, which is by the presence of defined

amounts of a certain additive. No other ways of obtaining fuel oils having the desired property are disclosed. If the claim makes no mention of the additive, the claim is not fully supported by the description. Another example would consist in the claim not being consistent with the disclosure, for instance, due to contradictions between the elements contained in the claims and the description. One other example would be that, having regard to the description and the drawings, the scope of the claims covers an area which was not recognized by the applicant, for example, mere speculation of possibilities that have not been explored yet.

- 5.56 A claim may broadly define a feature in terms of its function, even where only one example of the feature has been given in the description, if the person skilled in the art would appreciate other means that could be used for the same function. For example, "terminal position detecting means" in a claim might be supported by a single example comprising a limit switch, it being apparent to the person skilled in the art that, for example, a photoelectric cell or a strain gauge could be used instead. In general, however, if the entire contents of the application are such as to convey the impression that a function is to be carried out in a particular way, with no intimation that alternative means are envisaged, and a claim is formulated in such a way as to embrace other means, or all means, of performing the function, then the claim does not comply with the support requirement. Furthermore, it may not be sufficient if the description merely states in vague terms that other means may be adopted, if it is not reasonably clear what they might be or how they might be used.
- 5.57 Characterization of a chemical compound solely by its parameters may be appropriate in certain cases (see paragraph 5.36). Characterization of a chemical compound by its parameters is fully supported by the description only when the invention is described by sufficient relevant identifying characteristics which provide evidence that the applicant recognized and described the claimed invention at the time of filing, such as by a description of partial structure, physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between structure and function, or a combination of these characteristics.
- 5.58 Compliance with the sufficiency requirement of Article 5 and the requirement for support for the claims in the disclosure of Article 6 are determined independently. In some cases, where the claim is too broad to be supported by the description and drawings, the disclosure may also be insufficient to enable a person skilled in the art to carry out the claimed invention. Thus there may be non-compliance with both the requirement concerning the relationship of the claims to the disclosure and the sufficiency requirement. See paragraph 4.12.

Appendix to Chapter 5

Multiple Dependent Claims

- A5.16 The International Searching and Preliminary Examining Authorities have divergent practices with regard to the treatment of multiple dependent claims. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.
- A5.16[1] A dependent claim which refers to more than one other claim should refer to them only alternatively. Multiple dependent claims cannot form a basis for other multiple dependent claims.
- A5.16[2] A dependent claim which refers to more than one other claim may refer to them either alternatively or cumulatively. Multiple dependent claims may form a basis for other multiple dependent claims.

Interpretation of Claims

A5.[20] The International Searching and Preliminary Examining Authorities have divergent practices with regard to whether the description can provide special definitions of

terms that are used in the claims. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.

A5.20[1] Where the description provides a special meaning by way of, for example, defining a term appearing in the claim, that definition should be used for the interpretation of the claim. The claims should not be limited in their meaning by what is explicitly disclosed in the description and drawings. The claims should not be limited by the scope of the examples of the claimed invention contained in the description. Further, if the wording of the claims needs interpretation, the description and the drawings, and the general knowledge of a person skilled in the art on the filing date are taken into account.

A5.20[2] If the description gives the words in a claim a special meaning, the examiner should, so far as possible, require the claim to be amended whereby the meaning is clear from the wording of the claim alone. The claim should also be read with an attempt to make technical sense out of it. Such a reading may involve a departure from the strict literal meaning of the wording of the claims.

Use Claims

A5.21 In some International Searching and Preliminary Examining Authorities, for purposes of international search and examination, a "use" claim of the form such as "the use of substance X as an insecticide" or "substance X when/whenever used as an insecticide" should be regarded as equivalent to a "process" claim of the form "a process of killing insects using substance X." (However, it should be noted that in certain designated/elected States, "when/whenever used" claims are considered for the purposes of the national law to be improper process claims which lack clarity and constitute excluded subject matter.) Before such Authorities, a claim of the form indicated should not be interpreted as directed to the substance X recognizable (for example, by further additives) as intended for use of an insecticide. Similarly, a claim for "the use of a transistor in an amplifying circuit" would be equivalent to a process claim for the process of amplifying, using a circuit containing the transistor and should not be interpreted as being directed to "an amplifying circuit in which the transistor is used," nor to "the process of using the transistor in building such a circuit."

Product by Process Claims

A5.26 The International Searching and Preliminary Examining Authorities have divergent practices with regard to the search and examination of product by process claims. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.

A5.26[1] Where a claim defines a product in terms of the process by which the product is made, the claim should be construed as a claim to the product *per se* that possesses the characteristics derived from the manufacturing process stated in the claim. Therefore, the patentability of a product defined by a product-by-process claim does not depend on its method of production. A product is not rendered novel merely by the fact that it is produced by means of a new process. If the product in such a claim is the same as, or obvious from, a product described in an item of prior art, the claim is unpatentable even though the product described in the item of prior art was made by a different process.

A5.26[2] Where a claim defines a product in terms of the process by which the product is made, the claim relates to, and would be anticipated by, only a product which has been actually produced by the process.

Conciseness

A5.42 The International Searching and Preliminary Examining Authorities have divergent practices with regard to whether claims, both individually and in their totality, are concise. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.

A5.42[1] Claims may be objected to as lacking conciseness when they are unduly multiplied or duplicative. Claims are unduly multiplied where, in view of the nature and scope of the invention, an unreasonable number of claims are presented which are repetitious and multiplied, the net result of which is to confuse rather than to clarify. The claims should not be unduly multiplied so as to obscure the definition of the claimed invention in a maze of confusion. However, if the claims differ from one another and there is no difficulty in understanding the scope of protection, an objection on this basis generally should not be applied. In addition, claims should differ from one another. If claims are presented in the same application that are identical or else are so close in content that they both cover the same thing, despite a slight difference in wording, an objection on the basis of conciseness may be proper. However, such an objection should not be applied if the change in wording results even in a small difference in scope between the two claims. Individual claims may be objected to as lacking conciseness only when they contain such long recitations or unimportant details that the scope of the claimed invention is rendered indefinite thereby.

A5.42[2] The number of claims must be considered in relation to the nature of the invention the applicant seeks to protect. 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. 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 claims should not obscure 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.

Chapter 6 Priority

The Right to Priority

Articles 11, 14; Rule 20

An international application is accorded as its international filing date the date on which it satisfies the requirements of Article 11. This date remains unchanged except in the special circumstances of later-filed drawings and sheets as provided in Article 14(2) and/or later-filed parts of the description, and claims and drawings that were missing at the time of original filing (see Rule 20.5(c), subject to the possibility of incorporation by reference without loss of the original filing date as provided by Rule 20.6) Rule 20.2. The international filing date may be the only effective date of the international application. It will be of importance for fixing the expiration of certain time limits and for determining the state of the art relevant for the purposes of the international search and examination.

Article 2(xi

6.02 However, in many cases, an international application will claim the right of priority of the date of filing of an earlier application. In this case, it is the priority date (that is, the filing date of the earlier application) which will be used to calculate certain time limits. Furthermore, it is the priority date which becomes the effective date for the purposes of the international examination, that is, the written opinion (of either the International Searching Authority or the International Preliminary Examining Authority) and the international preliminary examination report. Note that the relevant date for the purposes of the international search is always the international filing date. Paragraph 11.03 defines the "relevant date" for purposes of the international search while paragraphs 11.04 and 11.05 define the "relevant date" for purposes of the written opinion (whether prepared by the International Searching Authority or the International Preliminary Examining Authority) and the international preliminary examination report. See also paragraphs 17.29 and 18.16. Paragraph 15.01 defines "relevant prior art" for the purposes of the international search while paragraph 11.01 provides a general definition of prior art.

Article 8(1); Rules 2.4, 4.10, 26bis.2

6.03 For a valid claim to priority, several conditions must be satisfied. First, the earlier application whose priority is claimed must have been made by the applicant or his predecessor in title.; it must have been filed not more than 12 months before the filing date of the international application; and Next, the earlier application must have been "filed either in or for any country party to the Paris Convention for the Protection of Industrial Property or in or for any Member of the World Trade Organization that is not party to that Convention." The words "in or for" any country or Member mean that the earlier application the priority of which is claimed may be an earlier national, regional or international application. Furthermore, the international application must in general have been filed within 12 months from the filing of the earlier application (the "priority period"). However, a priority claim will not be considered void only because the international filing date is later than the date on which the priority period expired, provided that it is within two months from that date (Rule 26bis.2), for example, in order to take into account the possibility of the applicant being granted re-establishment restoration of rights in respect of the priority period either before the receiving Office in the international phase (Rule 26bis.3) or before the authorities of the designated states (Rule 49ter.2). The earlier application may be for a patent or for the registration of a utility model or for an inventor's certificate. So long as the contents of the earlier application were sufficient to establish a filing date, it can be used to create a priority date, no matter what the final disposition of the application may later be; for example, it may subsequently be withdrawn or held withdrawn. Other conditions to be satisfied for a valid claim of priority are mentioned in paragraphs 6.04 and 6.11 to 6.17.

Article 8(2)(a)

6.04 Normally, the application the priority of whose filing date is claimed must be the first application that has been filed for the invention. However, a subsequent application for

the same subject matter as the previous first application filed in or for the same State will be considered as the first application for priority purposes if, when this subsequent application was filed, the first application had been withdrawn, abandoned or refused, without being open to public inspection and without leaving any rights outstanding, and had not served as a basis for claiming priority. The examiner will not normally consider this question unless there is clear evidence of the existence of an earlier application as, for example, in the case of a United States continuation application. Where it is clear that an earlier application for the same subject matter exists, and where the priority right is important because of intervening prior art (see paragraph 6.06), the applicant should be invited to satisfy the examiner that there were no rights outstanding in the earlier application in respect of the subject matter of the application being examined.

Article 8(1)

6.05 An international application may claim rights of priority based on more than one earlier application ("multiple priorities"), even if they originate in different countries. The earliest application must have been filed not more than 12 months before the date of filing of the international application. An element of an international application will be accorded the priority date of the earliest priority application which discloses it. If, for instance, the international application describes and claims two embodiments (A and B) of an invention. A being disclosed in a French application and B in a German application, both filed within the preceding 12 months, the priority dates of both the French and German applications may be claimed for the appropriate parts of the international application; embodiment A will have the French priority date and embodiment B the German priority date. If an international application is based on one earlier application disclosing a feature C and a second earlier application disclosing a feature D, neither disclosing the combination of C and D, a claim to that combination will be entitled only to the date of filing of the international application itself. In other words, it is not permitted to make a mosaic of the priority documents. An exception might arise where one priority document contains a reference to the other and explicitly states that features from the two documents may be combined in a particular manner.

Determining Priority Dates

- As a general rule, the examiner, in preparing a written opinion or an international preliminary examination report, should not make any investigation as to the validity of a right to priority, in which case, Box No. II ("Priority") of the opinion or report would not normally be included (see paragraph 17.28). However, the priority right assumes importance if subject matter relevant with regard to the determination of novelty or inventive step (non-obviousness) of the claimed invention:
- (i) has been published within the meaning of Rule 64.1 on or after the priority date claimed and before the international filing date;
- (ii) forms part of the content of a non-written disclosure within the meaning of Rule 64.2, that is, a non-written disclosure which occurred before the priority date and which was indicated in a written disclosure in the period between, and including, the priority date and the international filing date; or
- (iii) forms part of the content of an application or patent within the meaning of Rule 64.3, that is, an application or patent which was published on or after that date but was filed earlier than the international filing date or claimed the priority of an earlier application which was filed prior to the international filing date.

In such cases (that is, cases where the art in question would be relevant if of earlier date), the examiner must satisfy himself that the priority date(s) claimed may be accorded to the appropriate parts of the international application he is examining and, where appropriate, will also consider the validity of any priority date claimed for the application or patent within the meaning of Rule 64.3 (see also Rule 70.10, last sentence).

- When the examiner needs to consider the question of priority date, he should bear in mind all the matters which are mentioned in paragraphs 6.03 to 6.05. He should also remember that, to establish a priority date, it is not necessary that all of the elements of the invention for which priority is claimed should be found among the claims in the previous application. It is sufficient that the documents of the previous application taken as a whole specifically disclose such elements. The description and any claims or drawings of the previous application should, therefore, be considered as a whole in deciding this question, except that account should not be taken of subject matter found solely in that part of the description referring to prior art, or in an explicit disclaimer.
- 6.08 The requirement that the disclosure must be specific means that it is not sufficient if the elements in question are merely implied or referred to in broad and general terms. A claim to a detailed embodiment of a certain feature would not be entitled to priority on the basis of a mere general reference to that feature in a priority document. Exact correspondence is not required, however. It is enough that, on a reasonable assessment, there is in substance a disclosure of the combination of all the important elements of the claim.
- 6.09 The basic test to determine whether a claim is entitled to the date of a priority document is the same as the test of whether an amendment to an application satisfies the requirement of Article 34(2)(b). That is to say, for the priority date to be allowed, the subject matter of the claim must be explicitly or inherently disclosed in the priority document, including any features implicit to a person skilled in the art. As an example of an implicit disclosure, a claim to apparatus including "releasable fastening means" would be entitled to the priority date of a disclosure of that apparatus in which the relevant fastening element was, say, a nut and bolt, or a spring catch or a toggle-operated latch, provided the general concept of "releasable fastening" is implicit in the disclosure of such element.
- 6.10 If the tests set out in paragraphs 6.07 to 6.09 are not satisfied in relation to a particular earlier application, then the relevant date of the claim will either be the priority date of the earliest application which satisfies the tests and does provide the required disclosure or, in the absence of such, will be the international filing date of the international application itself.

Claiming Priority

Article 11; Rule 4.10

6.11 An applicant who wishes to claim priority must state this on the request (Form PCT/RO/101) giving particulars of the previous filing, as specified in Rule 4.10 (see paragraph 6.13), although later correction of priority claims, including the addition or deletion of entire priority claims, is permitted under Rule 26*bis* within the time limits discussed in paragraph 6.16.

Rule 17.1

- 6.12 When making a claim to priority, the applicant must, in addition to giving the particulars of the previous filing, either:
- (i) submit the priority document to the International Bureau or to the receiving Office within 16 months of the priority date, unless it was already filed with the receiving Office together with the international application; or
- (i)(ii) where the priority document is issued by the receiving Office, request the receiving Office to prepare and transmit the document to the International Bureau; or
- (ii) (iii) request the International Bureau before international publication or the receiving Office to obtain the priority document from a digital library within 16 months of the priority date where the priority document is available from the digital library in accordance with the Administrative Instructions.

Any priority document submitted by the applicant which is received by the International Bureau after the expiration of that 16-month time limit will nevertheless be considered to

have been received by that Bureau on the last day of the 16-month time limit if it is received before the date of international publication of the international application. Where the priority document is issued by the receiving Office the applicant may, instead of submitting the priority document, request the receiving Office to transmit the priority document to the International Bureau, in which case the time limit for furnishing the priority document has been complied with if the applicant makes the request before the expiration of the 16-month time limit irrespective of when the priority document reaches the International Bureau.

- 6.13 The examiner should keep in mind that the form of the declaration (see paragraph 6.11) claiming the priority of one or more earlier applications under Article 8(1) is prescribed under Rule 4.10(a). The prescribed form of declaration includes the giving of the following indications:
- (i) the date on which the earlier application was filed, being a date falling within the period of 12 months preceding the international filing date;
 - (ii) the number of the earlier application;
- (iii) where the earlier application is a national application, the country party to the Paris Convention for the Protection of Industrial Property or the Member of the World Trade Organization that is not party to that Convention in which it was filed;
- (iv) where the earlier application is a regional application, the authority entrusted with the granting of regional patents under the applicable regional patent treaty;
- (v) where the earlier application is an international application, the receiving Office with which it was filed.
- 6.14 Where the earlier application is a regional application or an international application, the applicant may also indicate in the priority claim one or more countries party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed.
- 6.15 Where the earlier application is a regional application and at least one of the countries party to the regional patent treaty is neither party to the Paris Convention for the Protection of Industrial Property nor a Member of the World Trade Organization, the priority claim must indicate at least one country party to that Convention or one Member of that Organization for which that earlier application was filed.

Rule 26bis

6.16 It is clear from the provisions of Rule 26*bis* that the indications concerning a priority claim, if not made in the request (Form PCT/RO/101), must be furnished by the applicant to the International Bureau or to the receiving Office within 16 months of the priority date or, where correction or addition of a priority claim would cause a change in the priority date, 16 months from the priority date as so changed, whichever 16-month period expires first, provided that a notice correcting or adding a priority claim may, in any case, be submitted until the expiration of four months from the international filing date. The correction of a priority claim may include the correction or addition of any indication referred to in Rule 4.10.

Rules 66.7(a), and (b), 17.1(c), and (d)

6.17 If the examiner needs a copy of the priority document (see paragraph 6.06), the copy is supplied on request by the International Bureau, unless the International Bureau has not yet received the priority document (see paragraph 6.12), in which event the examiner may invite the applicant himself to furnish such a copy. If the priority document is not in the language, or one of the languages (if more than one) of the relevant Authority, the examiner may invite the applicant using Form PCT/IPEA/414 to furnish a translation of the priority document within two months of the invitation. In the meantime, any written opinion established while there is still time to furnish the priority document or translation thereof may proceed as if the priority had been validly claimed (see also paragraphs 11.05, 17.26 and 18.16); however, if the necessary priority document or its translation is not timely furnished,

any further written opinion or the international preliminary examination report may be established as if the priority had not been claimed. No designated Office may disregard the priority claim before giving the applicant an opportunity to furnish the priority document within a time limit which is reasonable under the circumstances. Furthermore, no designated Office may disregard the priority claim if the priority document is available to it from a digital library in accordance with the Administrative Instructions.

Chapter 7 Classification of International Applications

Definition

Rule 43.3

7.01 Classification involves the assigning of one or more classification symbols to a particular international application, whereby the technical subject of the invention of that application is identified. Every international application must be classified by the International Searching Authority according to the International Patent Classification system (IPC), and this chapter deals only with such classification.

Definitive Classification of the International Application

7.02 The classification of the international application is determined by the International Searching Authority. Classification symbols are applied to each application according to the current rules of the IPC. The IPC Guide can be accessed through the World Intellectual Property Organization WIPO web site at www.wipo.int.

Multiple Classifications

7.03 If the international application requires more than one classification symbol, then all such classifications are assigned in accordance with the IPC Guide.

Classification of Disclosure as Filed

7.04 The classification is determined without taking into consideration the probable content of the international application after any amendment, since this classification should relate to the disclosure in the published international application, that is, the application as *filed*. If, however, the examiner's understanding of the invention, or of the content of the application as *filed*, alters significantly as a result of the search (for example, as a result of prior art found, or because of the clarification of apparent obscurities), the classification should be amended accordingly.

Amended Classification in the Case of Later Published International Search Report

7.05 In case the international search report is not available in time for publication with the international application, and therefore is published separately, and the examiner finds it necessary to amend the original classification for the reasons given in paragraph 7.04, he includes the amended classification in the international search report, indicating, by adding the word "amended," that it replaces the one published on the international application. Such amendment of the classification should not be made unless the examiner is quite certain that it is necessary.

Classification When Scope Is Obscure

7.06 When the scope of the invention is not clear, the classification has to be based on what appears to be the invention insofar as this can be understood. It may be necessary to amend the classification, at a later stage, if obscurities are removed by the search, as discussed in paragraph 7.04.

Lack of Unity of Invention

7.07 All claimed inventions must be fully classified, whether or not there is lack of unity of invention, since all are disclosed in the published international application. Each invention claimed is classified as set out in paragraphs 7.02 to 7.06.

Classification of International Applications Excluded from International Search

7.08 If the International Searching Authority finds that the international application relates to a subject matter which it is not required to search or that a meaningful search cannot be carried out (see Chapter 9), the classification is nevertheless made, to the extent

possible, and communicated to the International Bureau for the purposes of publication of the international application.

Chapter 8 Rule 91 – Obvious Errors-Mistakes in Documents

Chapter 8

Rule 91.1(a)-(e), Rule 91.2

- 8.01 Mistakes which are due to the fact that something other than that which was obviously intended were included in the contents of the international application or in a later submitted paper (for example, linguistic errors, spelling errors) may be rectified if a request for rectification is submitted within 26 months from the priority date and the necessary criteria are met. The mistake must be "obvious" in the sense that it is obvious to the competent authority:
- (i) <u>that something else was intended than what appears in the document concerned; and</u>
 - (ii) that nothing else could have been intended than the proposed rectification.
- 8.02 It must be clearly apparent to the competent authority that a mistake was made. No special attributes are ascribed by Rule 91 to the person in the competent authority making the finding whether an alleged mistake is obvious and thus rectifiable. It is thus left to the practice of each authority as to whether, for example, the notional reader should in all cases be an average person with no special skills or, particularly in cases of mistakes in the description, claims and drawings, a "person skilled in the art". The competent authority makes the determination whether a mistake is rectifiable.
- 8.03 In the context of Rule 91, the word "authority" may, depending on the circumstances as set out in the Rule, refer to the receiving Office, the International Bureau, the International Searching Authority or the International Preliminary Examining Authority (see paragraph 8.12).

Rule 91.1(c)

- 8.04 The test for the rectification of an obvious mistake is a two-fold test:
 - (i) the recognition that there was indeed a mistake; and
- (ii) <u>an assessment as to whether the proposed rectification was the only meaning</u> which could have been intended.

In other words, it first must be apparent that a mistake has been made. Then it must be clear that nothing else could have been intended other than the proposed rectification.

Rule 91.1(d)

8.05 Examples of obvious mistakes that are rectifiable include linguistic errors, spelling errors and grammatical errors, so long as the meaning of the disclosure would not change if the rectification was made. An obvious mistake is not solely limited to such kinds of mistakes, but for the correction to the description, claims, or drawings, the finding by the competent authority as to whether an alleged mistake is obvious must be made only on the basis of the description, claims and drawings international application itself, without any reliance on extrinsic documents. The contents of priority documents should not be taken into account for the purposes of considering whether mistakes in the description, claims or drawings are obvious and thus rectifiable. Mistakes in a chemical or mathematical formula would not generally be rectifiable unless the correct formula was common knowledge.

Rule 91.1(c)

8.06 If a correction is not of this character (for example, if it involves cancellation of claims, omission of passages in the description or omission of certain drawings), it would not be authorized by the competent authority. It is noted that Rules 20.5 to 20.8 allow an applicant to request that the receiving Office replace a missing element or part of an application if the request included a statement of incorporation by reference under Rule 4.18 that is later confirmed in accordance with Rules 20.5 and/or 20.6 within the time limit under Rule 20.7. In

view of Rules 20.5 to 20.8, it should not be necessary for applicants to request rectification of the omissions of entire elements or sheets under Rule 91.

Rule 91.1(e)

8.06 In the case of a mistake:

- (i) in the request part of the international application or a correction thereof; or
- (ii) in a document other than the description, claims or drawings, or in a correction thereof, or in an amendment under Article 19 or 34;

the finding of the competent authority takes into account only the contents of the international application itself and, where applicable, the correction concerned, or in said document, together with any other document submitted with the request, correction or document, as the case may be, any priority document in respect of the international application that is available to the authority in accordance with the Administrative Instructions, and any other document contained in the competent authority's international application file at the applicable date under paragraph 8.07. Extrinsic evidence filed with the request for rectification is not permitted to be used as such evidence would be provided too late according to Rule 91.1(f) (see paragraph 8.08)

Rule 91.1 (f)

- 8.07 The applicable date as at which it must be determined whether a request for rectification of an obvious mistake should be approved is:
- (i) where the alleged mistake is in a part of the international application as filed (including the request see Article 3(2)): the international filing date;
- (ii) where the alleged mistake is in a document other than the international application as filed, including a mistake in a correction or an amendment of the international application: the date on which the document containing the alleged mistake was received.

Where the alleged mistake is in a part of the international application as filed, the two-part rectification test discussed in the paragraph 8.04 must be applied as at the international filing date. Knowledge that came into being after the international filing date may not be used to rectify such a mistake. Where the alleged mistake is in another document, the two-part test must be applied as at the date on which the document was filed. Knowledge that came into being after that date may not be relied upon.

Mistakes that Cannot Be Rectified Under Rule 91

8.08 Under Rule 91.1(g), a mistake shall not be rectified if:

Rule 66.5 and 91.1(g)(i)

(i) the mistake lies in the omission of one or more entire elements of the international application referred to in Article 3(2) (request, description, claims, drawings, or abstract) or one or more entire sheets of the international application;

Rule 91.1(g)(ii)

(ii) the mistake is in the abstract;

Rule 91.1(a)(iii)

(iii) the mistake is in an amendment under Article 19, unless the International Preliminary Examining Authority is competent to authorize the rectification because a demand for international preliminary examination has been made and has not been withdrawn and the date on which international preliminary examination is to start in accordance with Rule 69.1 has passed; or

Rules_26bis.2(e) and 91.1(g)(iv)

(iv) the mistake is in a priority claim or in a notice correcting or adding a priority claim under Rule 26*bis*.1(a), where the rectification of the mistake would cause a change in the priority date.

Missing Elements or Sheets

8.09 However, it is noted that provisions for providing a missing element or sheet to the receiving Office are provided in Rules 20.5 to 20.8 (see also paragraph 0). An applicant may, under Rule 38.3, propose modifications to the abstract established by the International Searching Authority. Changes to the priority claim, other than a change in the priority date, may be made under either Rule 91 or Rule 26*bis*.1(a).

Correction of Priority Claims

Rule 26bis.2(e)

8.10 Corrections or additions of priority claims that would affect the priority date may only be effected in accordance with Rule 26bis. However, where the applicant wishes to correct or add a priority claim but the time limit under Rule 26bis.1 has expired, the applicant may request the International Bureau to publish information concerning the matter. Any such request must be made prior to the expiration of 30 months from the priority date and is subject to the payment of a special fee.

Transmittal to Another Authority of a Request for Rectification

Rule 91.1(b)

- 8.11 The following authorities are competent to authorize rectifications in the international application and associated papers:
- (i) <u>if the mistake is in the request part of the international application or in a correction thereof: the receiving Office;</u>
- (ii) <u>if the mistake is in the description, claims or drawings or in a correction</u> thereof: the International Searching Authority, unless the International Preliminary Examining Authority is competent under item (iii);
- (iii) if the mistake is in the description, claims, drawings or in a correction thereof, or in an amendment under Article 19 or 34, where a demand for international preliminary examination has been made and has not been withdrawn and the date on which the international preliminary examination is to start in accordance with Rule 69.1 has passed: the International Preliminary Examining Authority:
- (iv) in the case of a mistake in a document not referred to in items (i) to (iii) submitted to the receiving Office, the International Searching Authority, the International Preliminary Examining Authority or the International Bureau, other than a mistake in the abstract or in an amendment under Article 19: that Office, Authority or Bureau, as the case may be.
- 8.12 If an International Authority receives a request for rectification of an obvious mistake in the request (where that International Authority is not also the receiving Office) or where it receives any other paper for which it is not the authority competent to authorize the rectification, it transmits that request together with any proposed replacement sheet to the appropriate authority, as listed above, and informs the applicant accordingly. It may, instead of transmitting the request, inform the applicant that the request should be sent to the authority competent to rectify the mistake. For the language(s) in which a request for rectification must be submitted, see Rule 12.2(b).

Invitation to the Applicant to Request Rectification

Rule 91.1(h)

8.13 If an International Authority discovers what appears to be an obvious mistake in the international application or any other paper submitted by the applicant, it may (optionally using Form PCT/ISA/216 or PCT/IPEA/411, respectively as applicable) invite the applicant to submit a request for rectification to the authority competent to authorize the rectification (Rule 91.1(b) and (h)). Although Rule 91.1(h) allows the International Authorities to invite rectifications, it is not expected that such invitations will be issued since any mistake which

can be rectified under Rule 91 will not be an impediment to establishing the search report and should not affect the substance of any written opinion or international preliminary examination report.

Submission and Processing of a Request for Rectification

Rule 91.2

8.14 A request for rectification must be submitted to the competent authority within 26 months from the priority date. A request for rectification must specify the mistake to be rectified and the proposed rectification, and may, at the option of the applicant, contain a brief explanation.

Rule 91.3; Section 511

8.15 Where a request for rectification is submitted to the International Searching Authority and that Authority is competent to authorize the rectification, the Authority considers whether the mistake is rectifiable under Rule 91.1, marks the documents in accordance with Section 511 and completes Form PCT/ISA/217. The International Searching Authority forwards the request for rectification and Form PCT/ISA/217 to the receiving Office, the International Bureau and the applicant.

Rule 91.1

8.16 During the international preliminary examination procedure, a request for rectification of an obvious mistake in the international application may be made by the applicant of his own volition. In addition, the examiner, upon study of the international application (other than the request) and any other papers submitted by the applicant, might also note obvious mistakes.

Rule 91.3; Section 607

8.17 Where a rectification of an obvious mistake is authorized or refused by the International Preliminary Examining Authority, the Authority promptly notifies the applicant of the authorization or refusal using Form PCT/IPEA/412 and, in the case of refusal, of the reasons therefor. The International Preliminary Examining Authority marks the request as set forth in Section 607 and sends a copy of the request for rectification and the Form PCT/IPEA/412 to the International Bureau and the applicant.

Authorization and Effect of Rectifications

Rule 43.6bis(a)

8.18 An authorized rectification of an obvious mistake under Rule 91.1 must, subject to paragraph 8.19, be taken into account by the International Searching Authority for the purpose of the international search (including the preparation of both the international search report and the written opinion of the International Searching Authority) unless the rectification is authorized by, or notified to International Searching Authority after it has begun to draw up the international search report. The international search report indicates that the rectification has been taken into account, subject to paragraph 8.19.

Rule 43.6bis(b), Section 413

8.19 The international search report, if possible, indicates whether the rectification of an obvious mistake has been taken into account in the situation where the processing or examination of the international application has already started prior to the date on which that Office is notified under Rule 91.3(a) of the authorization of the rectification by the competent authority. If the report fails to indicate whether the rectification of an obvious mistake was taken into account, the International Searching Authority notifies the International Bureau accordingly, and the International Bureau proceeds as provided for in the Administrative Instructions.

Rule 48.2(a)(vii), Rule 91.3(d)

8.20 <u>Upon the applicant's request, if the competent authority refuses to authorize a rectification under Rule 91.1, the International Bureau publishes the request for rectification, the reasons for the refusal by the authority and any further brief comments that may be</u>

submitted by the applicant, if possible, together with the international application (where the request is received by the International Bureau before the end of the technical preparations for publication). Such a request must be submitted within 2 months from the date of the refusal and is subject to the payment of a special fee.

Rule 48.2(k)

8.21 If a request for publication under Rule 91.3(d) was received by the International Bureau after completion of technical preparations for the international publication, the request for rectification of an obvious mistake, any reasons and any comments is promptly published after the receipt of such request for publication. Additionally, the front page is republished.

Rule 48.2(a)(vii)

8.22 <u>If the authorization of a rectification of an obvious mistake was received or given by the International Bureau before the completion of the technical preparations for international publication, the international publication includes the rectification.</u>

Rule 48.2(i)

8.23 If the authorization of a rectification of an obvious mistake is received by or, where applicable, given by the International Bureau after completion of the technical preparations for the international publication, a statement reflecting all the rectifications is published, together with the sheets containing the rectifications, or the replacement sheets and the letter furnished under Rule 91.2. Additionally, the front page is republished.

Effective Date of Rectification

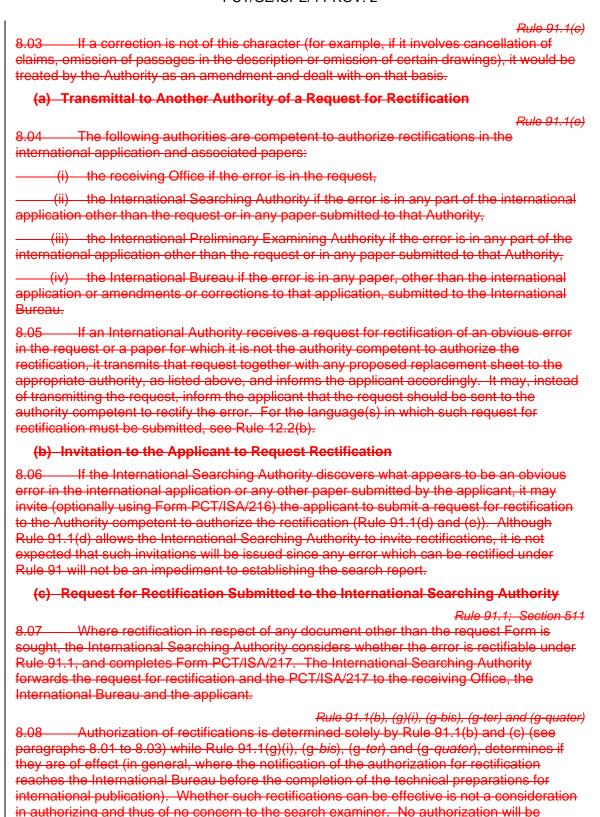
Rule 91.3 (c)

- 8.24 Where the rectification of an obvious mistake has been authorized, it is effective:
- (i) in the case of a mistake in the international application as filed: from the international filing date;
- (ii) in the case of a mistake in a document other than the international application as filed, including a mistake in a correction or an amendment of the international application: from the date on which the document was submitted.

Thus, the rectification of an obvious mistake in the international application as filed is effective from the international filing date (that is, not from the date on which the rectification is proposed) and the rectification of a mistake in another document is effective from the date on which the document concerned was submitted (that is, not from the date on which the rectification was proposed).

(ii) that anyone would immediately recognize that nothing else could have been intended other than the offered rectification.

8.02 Examples of obvious errors that are rectifiable include linguistic errors, spelling errors and grammatical errors so long as the meaning of the disclosure does not change upon entry of the rectification. Errors in chemical or mathematical formulae would not generally be rectifiable unless the correct formulae would be common knowledge to anyone.



approved once publication has occurred.

(d) Request for Rectification Submitted to the International Preliminary Examining Authority

Rules 66.5, 91.1(b)

8.09 Subject to authorization (see paragraph 8.10), rectification of obvious errors in the international application can be made at the request of the applicant of his own volition. In addition, the examiner, upon study of the international application (other than the request) and any other papers submitted by the applicant, might also note obvious errors. Although Rule 91 allows the International Preliminary Examining Authority to invite applicants to submit a request for rectification (optionally using Form PCT/IPEA/411), it is not foreseen that such invitations will be issued since any error which can be rectified under Rule 91 will not be an impediment to establishing the international preliminary examination report.

Rule 91.1(e), (f) and (g)(ii); Section 607

8.10 Rectification of an obvious error cannot be made before the International Preliminary Examining Authority without the express authorization of that Authority. The Authority is permitted to authorize rectification of such errors in a part of the international application other than the request or in any papers submitted to it. The examiner may only authorize rectification of obvious errors up to the time the international preliminary examination report is established. The time within which requests for rectification can be made to that Authority is limited accordingly. Any Authority which authorizes or refuses any rectification promptly notifies the applicant of the authorization or refusal using Form PCT/IPEA/412 and, in the case of refusal, of the reasons therefor. The International Preliminary Examining Authority sends a copy of the request for rectification and the Form PCT/IPEA/412 to the International Bureau.

PART III

EXAMINER CONSIDERATIONS COMMON TO BOTH THE INTERNATIONAL SEARCHING AUTHORITY AND THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Chapter 9

Exclusions from, and Limitations of, International Search and International Preliminary Examination

Introduction

Articles 17(2), 34(4)

9.01 The aim of the International Searching and Preliminary Examining Authorities 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 report is issued, or in which the search report, 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 9.02 to 9.18 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 9.19 to 9.39 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, that is, 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 parts of the application are not in compliance with the prescribed requirements, a search should be performed recognizing that the non-compliance may have to be taken into account for determining the extent of the search. See paragraphs 9.19 to 9.30 for further discussion and examples on this issue.

Excluded Subject Matter

Articles 17(2)(a)(i), 34(4)(a)(i); Rules 39, 67

- Rule 39 specifies certain subject matter which an International Searching Authority is not required to search. Rule 67 sets out an identical list of subject matter, on which an International Preliminary Examining Authority is not required to perform an international preliminary examination (and also, in accordance with Rule 43*bis*.1(b), for which the International Searching Authority is not required to establish a written opinion concerning novelty, inventive step and industrial applicability). While the subject matter in these Rules may be excluded from search or examination, there is no requirement that it be excluded. Depending on the policy of the Authority, such subject matter may be searched or examined. Any such subject matter which a particular Authority is prepared to search or examine is set forth in an Annex to the Agreement between that Authority and the International Bureau. Accordingly, the subject matter excluded from the international search or international preliminary examination may vary between the various Authorities.
- 9.03 Any such restriction to the search, or to the international preliminary examination should be accompanied by a reasoned explanation in the written opinion or international preliminary examination report issued by the Authority. If no search is to be carried out the search examiner will complete Form PCT/ISA/203 (Declaration of Non-Establishment of International Search Report). As a general principle, a search is to be carried out wherever practicable.

9.04 The following paragraphs relate to subjects that may be excluded from international search or preliminary examination according to Rules 39 and 67. Practices differ among the Authorities regarding the exclusions issue. Some Authorities use an approach involving a "practical application" while others use an approach involving a "technical character." Each Authority may use the approach that is consistent with its own practice. Paragraphs 9.05, 9.07 and 9.11 to 9.15 use both terms to accommodate these alternative practices. For the purposes of these paragraphs, the term "practical application" should be understood to mean a characteristic that the claimed invention, when viewed as a whole, has a practical application providing a useful, concrete and tangible result. "Technical character" should be understood to mean that the claimed invention must relate to a technical field, must be concerned with a technical problem and must have technical features in terms of which the matter for which protection is sought can be defined in the claim. However, it is noted that paragraphs 9.06 and 9.08 to 9.10, below, relate to exclusions that are not affected by these alternative practices.

Scientific and Mathematical Theories

Rules 39.1(i), 67.1(i)

9.05 The mere presence of scientific or mathematical theories in claims does not immediately exclude the claims from search or preliminary examination. When viewing the claims as a whole, if the theories are applied or implemented to produce a practical application or to have technical character, search and preliminary examination is required since the result is not purely abstract or intellectual. Scientific theories are a more generalized form of discoveries. For example, the physical theory of semi-conductivity would be excluded, whereas new semiconductor devices and processes for manufacturing would require search and preliminary examination. Mathematical theories are a particular example of the principle that purely abstract or intellectual methods are excluded. For example, a shortcut method of division would be excluded but a calculating machine designed to operate accordingly would require search and preliminary examination.

Plant or Animal Varieties or Essentially Biological Processes for the Production of Plants and Animals, Other Than Microbiological Processes

Rules 39.1(ii). 67.1(ii)

9.06 While plant and animal varieties may be excluded from search, transgenic plants and genetically modified non-human animals, as well as methods of making these types of inventions would be searched and examined. The question whether a process is "essentially biological" is one of degree, depending on the extent to which there is technical intervention by man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded. For example, a method of selectively breeding horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological. However, a method of treating a plant characterized by the application of a growth-stimulating substance or radiation would not be essentially biological since, although a biological process is involved, the essence of the claimed invention is technical. Similarly, methods of cloning or genetically manipulating non-human animals are not essentially biological processes and would be searched and examined. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded. The exclusion referred to above does not apply to microbiological processes or the products thereof. The term "microbiological process" is to be interpreted as covering not only industrial processes using microorganisms but also processes for producing microorganisms, for example, by genetic engineering. The product of a microbiological process may also be subject to search and preliminary examination (product claim). Propagation of the product of a microbiological process itself is to be construed as a microbiological process for the purposes of Rules 39 and 67; consequently, the product can be protected per se as it is a product obtained by a microbiological process. The term "product of a microbiological process" covers plasmids and viruses also.

Schemes, Rules or Methods of Doing Business, Performing Purely Mental Acts or Playing Games

Rules 39.1(iii), 67.1 (iii)

9.07 Schemes, rules or methods of doing business, performing purely mental acts or playing games are further examples of items of an abstract or intellectual character. Note that it is not the particular art involved or classification of claimed invention that is determinative of exclusion, but rather whether the claimed invention is of an abstract character. Specific guidance where divergent practices exist is set forth in the appendix to this chapter.

Methods for Treatment of the Human or Animal Body by Surgery or Therapy; Diagnostic Methods Practiced on the Human or Animal Body

Rules 39.1(iv), 67.1(iv)

- 9.08 Methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods practiced on the human or animal body are further subject matter on which an Authority is not required to carry out international search or preliminary examination. Search and preliminary examination should, however, be conducted for surgical, therapeutic or diagnostic instruments or apparatus for use in such methods. Search and preliminary examination should also be conducted for new products, particularly substances or compositions for use in these methods of treatment or diagnosis.
- 9.09 It should be noted that Rules 39.1(iv) and 67.1(iv) exclude only certain treatment by surgery or therapy or certain diagnostic methods. It follows that other methods of treatment of live human beings or animals (for example, treatment of a sheep in order to promote growth, to improve the quality of mutton or to increase the yield of wool) or other methods of measuring or recording characteristics of the human or animal body are appropriate for international search and preliminary examination, provided that (as would probably be the case) such methods are not of essentially biological character (see paragraph 9.06). For example, an application containing claims directed to the cosmetic treatment of a human by administration of a chemical product should be searched and examined. A search or preliminary examination on a cosmetic treatment involving surgery need not, however, be carried out (see the last sentence of paragraph 9.10).
- A treatment or diagnostic method, to be excluded, must actually be limited to being carried out on the living human or animal body. A treatment of or diagnostic method practiced on a dead human or animal body would therefore not be excluded from international search and preliminary examination by virtue of Rules 39(1)(iv) and 67.1(iv). Treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon would not be excluded from the search or preliminary examination insofar as these tissues or fluids are not returned to the same body. Thus, the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body could be excluded. Diagnostic methods comprise the carrying out of an investigation for medical purposes into the state of a human or animal body, so that a method of measuring the blood pressure of a body or a method of obtaining information regarding the internal state of a body by passing X-rays through the body could be excluded from international search or preliminary examination. A treatment by therapy implies the curing of a disease or malfunction of the body; prophylactic methods, for example, immunization, are considered to be therapeutic treatments and thus may be excluded. Surgery is not limited to healing treatments, being more indicative of the nature of the treatment; methods of cosmetic surgery may thus be excluded from search or preliminary examination.

Rules 39.1(v), 67.1(v)

- Any presentation of information characterized solely by the content of the information would be excluded under Rules 39 and 67. This applies, whether the claim is directed to the presentation of the information per se (for example, by acoustical signals, spoken words, visual displays), to information recorded on a carrier (for example, books characterized by their subject, gramophone records characterized by the musical piece recorded, traffic signs characterized by the warning thereon, magnetic computer tapes characterized by the data or program recorded), or to processes and apparatus for presenting information (for example, indicators or recorders characterized solely by the information indicated or recorded). If, however, the presentation of encoded information has a technical character or both a structural and functional relationship to the information carrier, process or apparatus, these should be examined as the subject matter relates to the information carrier or to the process or apparatus for presenting the information. Such examples would include a measuring device with volumetric markings having both a structural and functional relationship with a measuring receptacle providing for recalibration of the device depending on the quantities desired; a gramophone record characterized by a particular groove form to allow stereo recordings; or a diapositive with a sound track arranged at the side of it.
- Mere arrangements or compilations of data are generally excluded subject matter unless the arrangement or manner of presentation has technical character or a practical application. For example, a mere program listing itself is not capable of execution and represents merely the expression of the underlying idea rather than the application of that idea, and would thereby fall within this exclusion. A disembodied data structure that has no interaction with an underlying program would not require international search and examination, while a data structure embodied in a tangible medium that has a technical character or has a practical application should be subject to international search and examination. Further examples in which such a technical character or practical application may be present are: a telegraph apparatus or communication system characterized by the use of a particular code to present the characters (for example, pulse code modulation) and a measuring instrument designed to produce a particular form of graph for presenting the measured information. A computer system for searching gene sequences within a particular library of genetic data (the searching function goes beyond mere presentation of information) would have a technical character or a practical application as would a computer program capable of directing the display of three dimensional coordinates of a polypeptide and the atomic coordinates of a polypeptide Q. A computer readable media having the atomic coordinates of a polypeptide encoded thereon, however, would not have a technical character or practical application even though the data structure is embodied in a tangible medium. The examples below illustrate both excluded and non-excluded subject matter for arrangements or compilations of data in the field of bioinformatics.
- 9.13 Example 1: 3-D structural data of a protein per se
 - Claim 1. A computer model of protein P generated with the atomic coordinates listed in Fig. 1.
 - Claim 2. A data array comprising the atomic coordinates of protein P as set forth in Fig. 1 which, when acted upon by a protein modeling algorithm, yields a representation of the 3-D structure of protein P.

International search and examination are not required for claims 1 and 2. Both claims are directed to a disembodied data structure that has no interaction with an underlying program.

- 9.14 Example 2: In silico screening methods directed to a specific protein
 - Claim 1. A method of identifying compounds that can bind to protein P, comprising the steps of:

applying a 3-dimensional molecular modeling algorithm to the atomic coordinates of protein P shown in Fig. 1 to determine the spatial coordinates of the binding pocket of protein P; and

electronically screening the stored spatial coordinates of a set of candidate compounds against the spatial coordinates of the protein P binding pocket to identify compounds that can bind to protein P.

Claim 2. A database encoded with data comprising names and structures of compounds identified by the method of claim 1.

Claim 1 is directed to a method that has a technical character or practical application. Accordingly, international search and examination is required.

Claim 2 is directed to a disembodied data structure that has no interaction with an underlying program. Thus, international search and examination is not required.

Computer Programs, to the Extent That the Authority is not Equipped to Carry Out Search or Preliminary Examination on Such Programs

Rules 39.1(vi), 67.1(vi)

9.15 Computer programs are excluded subject matter to the extent that the Authority is not equipped to carry out search or preliminary examination on such programs. It should be noted at the outset that programs for computers can be expressed in many forms. Normally, claims that merely recite program code are excluded subject matter. However, to the extent that a natural language description of any computer-executable program, or a self-documented code, is included in the description and the claims, the Authority should be considered "equipped" to carry out a search and preliminary examination based on such a description subject to the relevant guidelines regarding the conditions as to exclusion. The Authorities have diverging practices with respect to determinations of exclusions as to computer programs. Specific guidance where divergent practices exist is set forth in the appendix to this chapter.

General Considerations in Assessing the Nature of the Subject Matter

Form of Claims

9.16 In considering whether subject matter under Rule 39 or 67 is present, there are two general points the examiner bears in mind. Firstly, he disregards the form or kind of claim and concentrates on the content in order to identify the subject matter. The first point is illustrated by the examples given in paragraph 9.15, which illustrate different ways of claiming a computer program. Secondly, any exclusion applies only to the extent that the international application relates to the excluded subject matter. This is illustrated, for instance, by a gramophone record distinguished solely by the music recorded thereon whereas if the form of the groove were modified so that the record, when used with an appropriate pickup mechanism, functioned in a new way (as in the first stereo record), the claimed subject matter could undergo international search and preliminary examination. For the application of Rules 39 and 67, the examiner should not apply the relevant criteria more restrictively than he would in the case of national applications.

Excluded Matter in Only Some Claims

Articles 17(2)(b), 34(4)(b)

9.17 Where the subject matter of only some of the claims is a subject excluded from the search and preliminary examination, this is indicated in the international search report, written opinion and the international preliminary examination report. Search and preliminary examination report. Search and preliminary examination report.

Cases of Doubt

9.18 In cases of doubt as to whether subject matter covered by a claim constitutes excluded subject matter, the Authority carries out the search or preliminary examination to the extent that this is possible using the available documentation.

Extent of Search and Preliminary Examination in Certain Situations

9.19 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, that is, no search at all is possible for a particular claim (see paragraph 9.01). However, in certain 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 is performed taking into consideration the non-compliance in determining the extent of the search. In such cases, the international search report and the written opinion then indicates how the description, claims, or drawings fail to comply with the prescribed requirements (see paragraphs 16.28, 16.29 and 17.34). In this indication, it is also noted by the International Searching Authority to what degree that non-compliance with the particular prescribed requirements has been taken into account for the purposes of determining the extent of the search, and this extent is indicated as precisely as possible. In general, a search should be carried out to the maximum extent practical.

Examples Where Search or Preliminary Examination Possible, with an Indication in the Written Opinion

9.20 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 crystal size than the addition of certain additives to the fuel oil and there is no common general knowledge of making fuel oils of this kind available to the person skilled in the art.

A search would first be made for the additive and fuel oils 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, that is, 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 not complying with the requirements of novelty and/or inventive step. The written opinion should also include any observations on non-prior art grounds (that is, requirements under Articles 5 and 6 such as sufficiency and support as well as industrial applicability). 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" (see paragraph 5.45); and/or (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 (see paragraphs 5.54 and 5.58). 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 purposes (see paragraph 16.72 (which indicates that the symbol "T" should be used for designating documents which are cited to show that the reasoning or the facts underlying the invention are incorrect), and paragraph 15.66 (directed to the category symbol to be used for subject matter which may be excluded from the international search)), which in this example involve a lack of support by the description. The International Searching

Authority should also include in the objection on non-prior <u>art</u> grounds an indication as to what degree these objections <u>have has</u> been taken into account for purposes of determining the extent of the search, and this extent should be indicated as precisely as possible, for example, the additive and fuel oils having defined amounts of the additive disclosed and/or the broad concept of fuel oil compositions having the desired property.

9.21 Example 2: Claim Characterized Solely by the Result to be Achieved

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

The description 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.

A search would first be made for the particular materials reacting 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 (that is, requirements under Articles 5 and 6 such as sufficiency and support, as well as industrial applicability). 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 steps of a process such that the scope of the invention is not set forth with a reasonable degree of clarity and particularity (paragraph 5.32), and (b) the phrase "improved properties" is a relative term (paragraph 5.34); and (2) the claim attempts to define the invention solely by the result to be achieved (paragraph 5.35). 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. The International Searching Authority should also include in the objection on non-prior art grounds an indication as to what degree these objections have has been taken into account for purposes of determining the extent of the search, and this extent should be indicated as precisely as possible, for example, the particular materials reacted in the particular manner.

9.22 Example 3: Claim Characterized Solely by Unusual Parameters

Claim 1: "A fat having a nausea index of less than or about 1.0."

The description discloses a number of fats that purportedly have a nausea index of less than 1.0 and a number of fats which have a nausea index greater than 1.0. Examples of fats having a nausea index of less than 1.0 include different mixtures of saturated and unsaturated fats. Examples of fats having a nausea index greater than 1.0 also include different mixtures of saturated and unsaturated fats. No other properties, for example, melting point, of these mixtures of fats are disclosed. The description discloses determining the nausea index by whipping the fat at a particular speed and temperature and measuring the viscosity of the whipped mixture at room temperature.

A search should first be made for the examples disclosed in the description as having a nausea index less than or about 1.0. If one of these examples is found in the prior art, an indication that the claim lacks novelty over the prior art would be made since the same material would be expected to have the same properties. Aside from any opinion on novelty and inventive step, the written opinion should indicate any observations on non-prior art grounds (that is, requirements under Articles 5 and 6 such as sufficiency and support, as well as industrial applicability). In this example, the claim would 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 5.45); and/or (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 (paragraphs 5.54 and 5.58); and (3) the claimed invention lacks clarity because the parameters cannot be clearly and reliably determined by indications in the description or by objective procedures which are recognized in the art (paragraph 5.36). 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 the 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, that is, inherent. For instance, in this example, perhaps a search using a parameter such as the extent of saturation could be made. The International Searching Authority should also include in the objection on non-prior art grounds an indication as to what degree these objections have has been taken into account for purposes of determining the extent of the search, and this extent should be indicated as precisely as possible, for example, the examples disclosed in the description and/or other known parameters or chemical or physical properties that imply the presence of the new parameter.

9.23 Example 4: Chemical Markush-Type Claim Encompassing Many Embodiments
In this example the claims encompass a very large number of possible embodiments
while the description discloses, and provides support for, only a relatively small
proportion of those embodiments (see paragraph 5.48).

In such cases, the search may be directed only towards claimed embodiments that relate to specifically disclosed compounds, or prepared or tested compositions and a structural generalization of these. The written opinion should also include observations on Articles 5 and 6 (sufficiency and support) describing specifically how the description provides support for only a relatively small proportion of the embodiments claimed. The International Searching Authority should also include in the objection on non-prior art grounds an indication as to what degree these objections have has been taken into account for purposes of determining the extent of the search, and this extent should be indicated as precisely as possible, for example the specifically disclosed compounds, or prepared or tested compositions, and a structural generalization of these.

9.24 Example 5: Chemical Markush-Type Claim with Many Options, Variables, Etc.

In this example, the claim contains so many options, variables, possible permutations and/or provisos, that the claim is rendered unclear and/or inconcise to the extent that it is not in compliance with Article 6 and Rule 6 (see paragraph 5.42).

In such cases, the search should be carried out for those parts of the claim that are clear and concise or to the extent that the claimed invention can be understood. For example, the search may be directed only towards claimed embodiments that relate to clearly disclosed compounds, or clearly prepared or tested compositions, and a structural generalization of these. The written opinion should also include observations on Article 6 (clarity and/or conciseness) describing specifically how the claims lack clarity and/or conciseness. The International Searching Authority should also include in the objection on non-prior art grounds an indication as to what degree these objections have has been taken into account for the purposes of determining the extent of the search, and this extent should be indicated as precisely as possible, for example the clearly disclosed compounds, or clearly prepared or tested compositions, and a structural generalization of these.

9.25 Example 6: Multitudinous Claims

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 they are not in compliance with Article 6 and Rule 6. However, there is a reasonable basis in the description, for

example from a particular passage, that clearly indicates which subject matter might be expected to be claimed.

The search should be based on the subject matter that would be expected to be claimed. In the written opinion, the claims should be objected to on the non-prior art grounds of lack of compliance with Article 6 and Rule 6. The International Searching Authority should also include in the objection on non-compliance with Article 6 and Rule 6 an indication to what degree these objections have has been taken into account for the purposes of determining the extent of the search, and this extent should be indicated as precisely as possible, for example by a brief written description of the searched subject matter, where possible citing a particular passage.

Examples of Exceptional Situations Where no Search at All is Possible for All or Some of the Claims

- 9.26 These examples relate to exceptional situations where, due to non-compliance of the application with the prescribed requirements, all or some of the claims cannot be meaningfully searched at all. This means that for cases where a meaningful search of all or some of the claims *is* possible, for example by taking into account a likely amendment to overcome the non-compliance, then such a search is carried out along the procedural lines set out in paragraph 9.19 and the examples in paragraphs 9.20 to 9.25.
- 9.27 When none of the claims can be meaningfully searched at all, since no likely amendment can be determined to overcome the non-compliance, the International Searching Authority makes a declaration in accordance with Article 17(2)(a)(ii). When only some of the claims cannot be meaningfully searched at all, however, an indication is made in the international search report in accordance with Article 17(2)(b) to this effect whereas the other claims will be searched as usual.

9.28 Example 1

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

Claim 1 is the only claim in the application. The description does not provide sufficient information about the invention to determine the subject matter to which the claim might reasonably be expected to be directed after it had been amended.

No search at all is possible. A declaration will be made in accordance with Article 17(2)(a)(ii). In the written opinion, the claim should be objected to on the non-prior art grounds of lack of compliance with Article 6 and Rule 6. The International Searching Authority should also include in the objection on non-compliance with Article 6 and Rule 6 an indication to what degree these objections have has been taken into account for the purposes of determining that no search at all is possible.

9.29 Example 2

Claim 1: "A composition of matter comprising kryptonite."

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

No search at all is possible for claim 1.

9.30 Example 3: Multitudinous Claims

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 they are not in compliance with Article 6 and Rule 6. There is no reasonable basis in the description or elsewhere,

for example from a particular passage, that indicates which subject matter would be expected to be claimed.

No search at all is possible.

Non Prior-Art Issues

- 9.31 More detailed discussions regarding the extent of the search can be found in Chapter 5. For searches regarding non-prior art issues, see paragraphs 15.02 and 15.53.
- 9.32 More detailed discussions of non-prior art concerns including clarity of the claims, conciseness and number of claims, support in the description, clear and complete disclosure of the claimed invention, sufficiency commensurate with the claims, and the relationship of claims to the disclosure can be found in paragraphs 5.31 to 5.58. A more detailed discussion of new matter can be found in paragraphs 20.20 and 20.21.

Industrial Applicability

9.33 If the opinion regarding industrial applicability is negative, then any prior art used to establish this should be cited in the search report and the reasoning set forth in the written opinion. In addition, if applicable, an indication with respect to novelty and inventive step is appropriate (see paragraph 17.42).

Informal Clarification

- Articles 17(2)(a)(ii) and (b), 34(4)(a)(ii), and (b)
- 9.34 In the event that the description, claims, or drawings fail to comply with a requirement, such as clarity or support of the claims by the description, to such an extent that no meaningful search can be made, the International Searching Authority may, where appropriate, ask the applicant informally for clarification before declaring that no international search report will be established. The examiner should keep in mind that without a search and written opinion of the International Searching Authority for all or part of the claimed subject matter, the international preliminary examination may be limited accordingly, and that the international search and written opinion of the International Searching Authority should be as useful as possible in the event that there is no demand for international preliminary examination. Similarly, if at the time of the first written opinion of the International Searching Authority or a written opinion of the International Preliminary Examining Authority, no opinion is possible on the question of novelty, inventive step (non-obviousness) or industrial applicability for all or part of the claimed subject matter, the examiner may ask the applicant informally for clarification. However, this does not mean that the applicant can be invited or allowed to file amendments before the International Searching Authority. An opinion may not be possible on the question of novelty, inventive step (non-obviousness) or industrial applicability for all or part of the claimed subject matter because the description or claims of the international application fail to meet the requirements of Articles 5 and 6 to such an extent that it is impossible to examine the claimed subject matter as to novelty, inventive step or industrial applicability. In such a case, the examiner examines the claimed subject matter to the extent possible and establishes a written opinion that reflects the inadequate support or other deficiencies for all or part of the claimed subject matter (see paragraphs 17.34 to 0). The examiner still makes any objections on non-prior art grounds in the written opinion even after informal clarification by the applicant, since the claimed subject matter was, and remains, unclear absent such clarification.
- 9.35 A need for clarification as referred to in paragraph 9.34 may arise where there are any kinds of defects in the claims which cause difficulty in determining the scope of the claims, for example, obscure, inconsistent, vague or ambiguous expressions. These kinds of defects include cases where the language used in the claims is not clear even after taking the description and drawings (if any) into account.

Unclear Claims

- 9.36 When the claimed subject matter taken as a whole includes alternatives, some of which are clear realizations of the invention, as well as other alternatives, which are unclear realizations of the invention, the search examiner searches the clear realization of the invention. With regard to the other, unclear realizations, the examiner determines the subject of search based on the subject matter which might reasonably be expected to be claimed by amendment taking into account the contents of the description and drawings and the common general knowledge in the relevant technical field and conduct the search based on the determined subject. The written opinion and international preliminary examination report establish opinions on the novelty, inventive step and industrial applicability of the claims to the extent that this is possible and explain the reasons why the remainder could not be properly assessed.
- 9.37 For example: if the invention relates to a combination of A + B + C + D in which B is unclear, a search would be performed insofar as the examiner can determine the subject matter to be searched as indicated in paragraph 9.36. However, if B is totally unclear such that it is impossible to determine the subject matter that may be reasonably expected to be claimed, no search would be performed. As another example, if the invention relates to a combination of (A1 or A2) + (B1 or B2), in which A2 is unclear but can be determined by the examiner as indicated in paragraph 9.36, then the entirety of the claim would be searched, including all alternative combinations. However, if A2 is totally unclear such that it is impossible to determine the subject matter that may reasonably be expected to be claimed, the alternative combinations (A1 + B1) and (A2 + B2) would still be searched.

Perpetual Motion

Article 17(2)(a)

9.38 Where an international application pertains to perpetual motion (*perpetuum mobile*), it is not necessarily excluded from searching. The International Searching Authority should endeavor to search such an application unless it is so unclear that the application of the principle of Article 17(2)(a) is required.

Sequence Listings

Rule 13ter.1(c) and (e)(a), (b); Section 208; Al Annex C

Another situation where a meaningful search or preliminary examination is not 9.39 possible may arise where the international application contains disclosure of one or more nucleotide and/or amino acid sequences but the applicant does not furnish a listing of the sequence in a written form, and/or a computer readable form, the International Searching Authority does not have available to it a copy of the sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions. The International Searching Authority requests the provision of such a sequence listing as soon as possible, before the search report and written opinion are established (see paragraphs 15.12 and 15.13 and paragraph 4.15). However if the listing is not provided or is not provided in the form required by the Standard, the Authority makes a meaningful search or preliminary examination to the extent that this is possible. For example, if a named protein is claimed, such a protein could be searched by its name rather than by its sequence. The same may occasionally apply also where a sequence listing is provided in paper (or .pdfimage file) form which does not comply with the standard provided for in Annex C of the Administrative Instructions and the International Searching Authority requires such a paper (or .pdfimage file) format for the purposes of the international search.

Declaration of Non-Establishment of International Search Report

Article 17(2)(a)

9.40 Where the subject matter of all claims constitutes a subject excluded from the search (see paragraphs 9.02 to 9.18) or where no meaningful search is possible for all of the claimed subject matter (see paragraphs 9.01 and 9.26 to 9.39), a declaration of

non-establishment of the international search report is issued pursuant to Article 17(2)(a) on Form PCT/ISA/203, indicating the reasons. Nonetheless, a written opinion is established, even though, in the absence of a search, it cannot address the questions of novelty and inventive step and may not be able to address other questions, such as that of industrial applicability. The detailed reasoning for not addressing those questions may be indicated in the written opinion by way of a reference to the full explanation in the declaration.

Multiple Dependent Claims

Article 17(2)(b), 34(4)(b); Rule 6.4(a)

9.41 Where an international application contains multiple dependent claims drafted in a manner different from that provided for in Rule 6.4(a), second and third sentences, the International Searching Authority may make an indication under Article 17(2)(b). Such an indication, however, is only made if and to the extent to which a meaningful search is not possible. The latter applies also in the case where the national law of the Office acting as International Searching Authority does not allow multiple dependent claims to be drafted in the said different manner. Such a case is also noted in the written opinion, and it will of course only be possible to establish a written opinion or international preliminary examination report on novelty and inventive step to the extent that the claims have in fact been searched.

Supplementary international search

9.41 The considerations in this chapter apply in general to supplementary international searches carried out under Rule 45*bis* in accordance with paragraphs 15.76 to 15.97. Additional limitations which can be applied by authorities are explained in paragraphs 15.87 and 15.88.

Appendix to Chapter 9

Excluded Subject Matter Regarding Schemes, Rules or Methods of Doing Business, Performing Purely Mental Acts or Playing Games

A9.07 The International Searching and Preliminary Examining Authorities have divergent practices with regard to the exclusion as to schemes, rules or methods of doing business, performing purely mental acts or playing games. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.

A9.07[1] The key question as to whether the invention falls within the exclusion is whether the claimed invention, when viewed as a whole, is of abstract character, or thereby does not provide a practical application having a useful, concrete and tangible result. For example, a theory or method of doing business or related to business function claimed in isolation without any practical application could be excluded from search and examination while a computer-implemented method or apparatus for performing a business-related function with a practical application would require search and preliminary examination. In addition, a game as an abstract entity defined by its rules could be excluded. However, a novel apparatus for playing a game would require international search and examination.

A9.07[2] These are items essentially of an abstract or intellectual character. In particular, a scheme for learning a language, a method for solving cross-word puzzles, a game (as an abstract entity defined by its rules) or a scheme for organizing a commercial operation would be excluded from both search and examination. However, if the claimed subject matter specifies an apparatus or technical process for carrying out at least part of the scheme, that scheme and the apparatus or process have to be searched and examined as a whole. In the particular case of a claim specifying computers, computer networks or other conventional programmable apparatus, or a program therefor, for carrying out at least some steps of a scheme, it is to be examined as a "computer-related invention" (see paragraph 9.15).

Excluded Subject Matter Pertaining to Programs for Computers

A9.[15] The International Searching and Preliminary Examining Authorities have divergent practices with regard to the exclusion for programs for computers. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.

The basic considerations here are exactly the same as for the other A9.15[1] exclusions listed in Rule 67, that is, whether the program claimed has a practical application providing a useful, concrete and tangible result. A mere program listing that describes an executable code that is not tangibly embodied as a record on a computer-readable carrier would be excluded subject matter and thereby not subject of international search and examination. Similarly, an executable program producing only an expression of an idea (such as a mathematical theory) even if tangibly embodied would also fall within this exclusion. However, a program containing executable code tangibly embodied on a computer-readable carrier which when executed has a practical application would not be excluded and should be searched and examined. In addition, a data-processing operation can be implemented either by means of a computer program or by means of special circuits, and the choice may have nothing to do with the inventive concept but be determined purely by factors of economy or practicality. The technology involved in executing the data-processing operation should not be dispositive as to the exclusion determination. With this point in mind, search and preliminary examination in this area should be performed on any computer program tangibly embodied in a computer-readable carrier providing a practical application (for example, a computer program product claim). International search and preliminary examination should not be denied merely on the grounds that a program is involved in its implementation. This means, for example, that program-controlled machines and program-controlled manufacturing and control processes should normally be regarded as subject matter on which an international search and preliminary examination can be carried out. It follows also that where the claimed subject matter is concerned only with the program-controlled internal working of a known computer, the subject matter could be searched and examined if it provides a practical application. As an example, consider the case of a known data-processing system with a small, fast-working memory and a larger, but slower, further memory. Suppose that the two memories are organized under program control in such a way that a process which needs more address space than the capacity of the fast-working memory can be executed at substantially the same speed as if the process data were loaded entirely in that fast memory. The effect of the program in virtually extending the working memory provides a practical application and would, therefore, require search and preliminary examination. Where search and preliminary examination on such claims is carried out, then, generally speaking, product, process and use claims should also be searched and examined. See, however, in this context, paragraphs 5.13 and 5.31.

A9.15[2] The basic considerations here are exactly the same as for the other exclusions listed in Rule 67, that is, whether the program claimed has technical character. A program producing only an expression of an idea (such as a mathematical theory) would fall within this exclusion. On the other hand, a data-processing operation can be implemented either by means of a computer program or by means of special circuits, and the choice may have nothing to do with the inventive concept but be determined purely by factors of economy or practicality. The technology involved in executing the data-processing operation should not be the determining factor for exclusion. With this point in mind, search and preliminary examination in this area should be performed on any computer program having technical character. International search and preliminary examination should not be denied merely on the grounds that a program is involved in the implementation. This means, for example, that program-controlled machines and program-controlled manufacturing and control processes should normally be regarded as subject matter on which an international search and preliminary examination can be carried out. It follows also that where the claimed subject matter is concerned only with the program-controlled internal working of a known computer, the subject matter could be searched and examined if it provides a technical effect which goes beyond the normal interaction between a program and a

computer. As an example, consider the case of a known data-processing system with a small, fast-working memory and a larger, but slower, further memory. Suppose that the two memories are organized under program control in such a way that a process which needs more address space than the capacity of the fast-working memory can be executed at substantially the same speed as if the process data were loaded entirely in that fast memory. The effect of the program in virtually extending the working memory provides a technical character and would, therefore, require search and preliminary examination of a claim relating to the program involved whatever is the form in which it is presented, for example, product, computer program product, process and use claims. See, however, in this context paragraphs 5.13 and 5.31.

Chapter 10 Unity of Invention

Determination of Unity of Invention

Article 17(3)(a): Rule 13: Section 206

10.01 An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Rule 13.2; Al Annex B, paragraph (b) Part 1(b)

10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

Rule 13.2

- 10.03 Lack of unity of invention may be directly evident "a priori," that is, before considering the claims in relation to any prior art, or may only become apparent "a posteriori," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity a priori as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present a priori as A is common to both claims. However, if it can be established that A is known or obvious (see Chapter 13 for guidance on obviousness), there is may be lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.
- 10.04 Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the applicant.
- 10.05 From the preceding paragraphs it is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority. However, the Authority should not raise objection of lack of unity of invention merely because the inventions claimed are classified in separate classification groups or merely for the purpose of restricting the international search to certain classification groups.

Al Annex B, Part 1(c)paragraph (c)

- 10.06 Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, in a situation like the plug and socket example in paragraph 5.19, a claim to the one part referring to the other cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim.
- 10.07 If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. For example, suppose claim 1 claims a turbine rotor blade shaped in a specified manner, while claim 2 is for a "turbine rotor blade as claimed in claim 1" and produced from alloy Z. Then no objection under Rule 13 arises either because alloy Z was new and its composition was not obvious and thus the alloy itself already contains the essential features of an independent possibly later patentable invention, or because, although alloy Z was not new, its application in respect of turbine rotor blades was not obvious, and thus represents an independent invention in conjunction with turbine rotor blades. As another example, suppose that the main claim defines a process for the preparation of a product A starting from a product B and the second claim reads: "Process according to claim 1 characterized by producing B by a reaction using the product C." In this case, too, no objection arises under Rule 13.1, whether or not the process for preparation of B from C is novel and inventive, since claim 2 contains all the features of claim 1. The subject matter of claim 2 therefore falls within claim 1. Equally, no problem arises in the case of a genus/ species situation where the genus claim avoids the prior art and satisfies the requirement of unity of invention. Moreover, no problem arises in the case of a combination/ subcombination situation where the subcombination claim avoids the prior art and satisfies the requirement of unity of invention and the combination claim includes all the features of the subcombination.
- 10.08 If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation. This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.
- 10.09 Alternative forms of an invention may be claimed either in a plurality of independent claims, or in a single claim (but see paragraph 5.18). In the latter case, the presence of the independent alternatives may not be immediately apparent. In either case, however, the same criteria are applied in deciding whether or not there is unity of invention, and lack of unity of invention may then also exist within a single claim. Where the claim contains distinct embodiments that are not linked by a single general inventive concept, the objection as to lack of unity of invention is raised. Rule 13.3 does not prevent an Authority 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 fee system applicable in that Authority.

10.10 Objection of lack of unity of invention does not normally arise if the combination of a number of individual elements is claimed in a single claim (as opposed to distinct embodiments as discussed in the paragraph immediately above), even if these elements seem unrelated when considered individually (see paragraph 15.31).

Illustrations of Particular Situations

Al Annex B. Part 1(d)paragraph (d)

- 10.11 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.

Combinations of Different Categories of Claims

Al Annex B, Part 1(e)paragraph (e)

- 10.12 The method for determining unity of invention under Rule 13 is 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 a 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.

A process is specially adapted for the manufacture of a product if it inherently results in the product and 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.

- 10.13 Thus, a process is 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.
- 10.14 Also an apparatus or means is considered "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.
- 10.15 More extensive combinations than those set forth in paragraph 10.12 should be looked at carefully to ensure that the requirements of both Rule 13 (unity of invention) and Article 6 (conciseness of claims) are satisfied. (See paragraph 5.42 regarding conciseness

of claims.) In particular, while a single set of independent claims according to one of the subparagraphs of paragraph 10.12 is always permissible, it does not require the International Authority to accept a plurality of such sets which could arise by combining the provisions of Rule 13.3 (which provides that the determination of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim), with the provisions set out in paragraph 10.12 (thus resulting in a set under paragraph 10.12 based on each of a number of independent claims in the same category under Rule 13.3 (see paragraphs 5.12 to 5.14)). The proliferation of claims arising from a combined effect of this kind should be accepted only exceptionally. For example, independent claims are permissible for two related articles such as a transmitter and receiver; however, it does not follow that, under paragraph 10.12, an applicant may include also, in the one international application, four additional independent claims: two for a process for the manufacture of the transmitter and the receiver, respectively, and two for use of the transmitter and receiver, respectively.

10.16 A single general inventive concept must link the claims in the various categories and in this connection the wording of paragraph 10.12 should be carefully noted. The link between product and process in subparagraph (i) is that the latter must be "specially adapted for the manufacture of" the former. Similarly, in paragraph 10.12, subparagraph (ii), the apparatus or means claimed must be "specifically designed for" carrying out the process. Likewise, in subparagraph (iii), the process must be "specially adapted for the manufacture of)" the product and the apparatus must be "specifically designed for" carrying out the process. In combinations (i)and (iii), the emphasis is on, and the essence of the invention should primarily reside in, the process. (See Examples below.)

"Markush Practice"

Al Annex B, Part 1(f)paragraph (f)

- 10.17 Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.
- (a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:
 - (A) all alternatives have a common property or activity, and
 - (B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or
 - (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- (b) In paragraph (a)(B)(1), 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, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.
- (c) In paragraph (a)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

- (d) The fact that the alternatives of a Markush grouping can be differently classified is not, taken alone, considered to be justification for a finding of a lack of unity of invention.
- (e) 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 invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity will be raised.

(See Examples below.)

Intermediate and Final Products

Al Annex B, Part 1(g)paragraph (g)

- 10.18 Rule 13.2 also governs the situation involving intermediate and final products.
- (a) 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.
- (b) Unity of invention is 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.
- (c) 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 must 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 as the final product or incorporates an essential element into the final product.
- (d) It is possible in a single international application to accept different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.
- (e) The intermediate and final products must not be separated, in the process leading from one to the other, by an intermediate that is not new.
- (f) If the same international application claims different intermediates for different structural parts of the final product, unity is not regarded as being present between the intermediates.
- (g) If the intermediate and final products are families of compounds, each intermediate compound must 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.

Al Annex B, Part 1(h)paragraph (h)

10.19 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 should not affect the decision on unity of invention.

Examples Concerning Unity of Invention

10.20 The application of the principles of unity of invention is illustrated by the following examples for guidance in particular cases.

Claims in Different Categories

10.21 Example 1

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The (method of) use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X. However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

10.22 Example 2

Claim 1: A process of manufacture comprising steps A and B.

Claim 2: Apparatus specifically designed for carrying out step A.

Claim 3: Apparatus specifically designed for carrying out step B.

Unity exists between claims 1 and 2 or between claims 1 and 3. There is no unity between claims 2 and 3 since there exists no common special technical feature between the two claims.

10.23 Example 3

Claim 1: A process for painting an article in which the paint contains a new rust inhibiting substance X including the steps of atomizing the paint using compressed air, electrostatically charging the atomized paint using a novel electrode arrangement A and directing the paint to the article.

Claim 2: A paint containing substance X.

Claim 3: An apparatus including electrode arrangement A.

Unity exists between claims 1 and 2 where the common special technical feature is the paint containing substance X or between claims 1 and 3 where the common special technical feature is the electrode arrangement A. However, unity is lacking between claims 2 and 3 since there exists no common special technical feature between them.

10.24 Example 4

Claim 1: Use of a family of compounds X as insecticides.

Claim 2: Compound X₁ belonging to family X.

Provided X_1 has the insecticidal activity and the special technical feature in claim 1 is the insecticidal use, unity is present.

10.25 Example 5

Claim 1: A process for treating textiles comprising spraying the material with a particular coating composition under special conditions (for example, as to temperature, irradiation).

Claim 2: A textile material coated according to the process of claim 1.

Claim 3: A spraying machine for use in the process of claim 1 and characterized by a new nozzle arrangement providing a better distribution of the composition being sprayed.

The process according to claim 1 imparts unexpected properties to the product of claim 2. The special technical feature in claim 1 is the use of special process conditions corresponding to what is made necessary by the choice of the particular coating. Unity exists between claims 1 and 2. The spraying machine in claim 3 does not correspond to the above identified special technical feature. Unity does not exist between claim 3 and claims 1 and 2.

10.26 Example 6

- Claim 1: A fuel burner with tangential fuel inlets into a mixing chamber.
- Claim 2: A process for making a fuel burner including the step of forming tangential fuel inlets into a mixing chamber.
- Claim 3: A process for making a fuel burner including casting step A.
- Claim 4: An apparatus for carrying out a process for making a fuel burner including feature X resulting in the formation of tangential fuel inlets.
- Claim 5: An apparatus for carrying out a process for making a fuel burner including a protective housing B.
- Claim 6: A process of manufacturing carbon black including the step of tangentially introducing fuel into a mixing chamber of a fuel burner.

Unity exists between claims 1, 2, 4, and 6. The special technical feature common to all the claims is the tangential fuel inlets. Claims 3 and 5 lack unity with claims 1, 2, 4, and 6 since claims 3 and 5 do not include the same or corresponding special technical feature as set forth in claims 1, 2, 4, and 6. Claims 3 and 5 would also lack unity with one another.

10.27 Example 7

- Claim 1: A high corrosion resistant and high strength ferritic stainless steel strip consisting essentially of, in percent by weight: Ni=2.0-5.0; Cr=15-19; Mo=1-2; and the balance Fe, having a thickness of between 0.5 and 2.0 mm and a 0.2% yield strength in excess of 50 kg/mm squared.
- Claim 2: A method of producing a high corrosion resistant and high strength ferritic stainless steel strip consisting essentially of, in percent by weight: Ni=2.0-5.0; Cr=15-19; Mo=1-2; and the balance Fe, comprising the steps of:
 - (a) hot rolling to a thickness between 2.0 and 5.0 mm;
 - (b) annealing the hot rolled strip at 800-1000°C under substantially no oxidizing conditions;
 - (c) cold rolling the strip to a thickness of between 0.5 and 2.0 mm; and
 - (d) final annealing the cold rolled strip at between 1120 and 1200°C for a period of 2-5 minutes.

Unity exists between product claim 1 and process claim 2. The special technical feature in the product claim is the 0.2% yield strength in excess of 50 kg/mm squared. The process steps in claim 2 inherently produce a ferritic stainless steel strip with a 0.2% yield strength in excess of 50 kg/mm squared. Even if this feature is not apparent from the wording of claim 2, it is clearly disclosed in the description. Therefore said process steps are the special technical feature which correspond to the limitation in the product claim directed to the same ferritic stainless steel with the claimed strength characteristics.

Claims in the Same Category

10.28 Example 8

Claim 1: Plug characterized by feature A.

Claim 2: Socket characterized by corresponding feature A.

Feature A is a special technical feature that is included in both claims 1 and 2 and therefore unity is present.

10.29 Example 9

Claim 1: Transmitter provided with time axis expander for video signals.

Claim 2: Receiver provided with time axis compressor for video signals received.

Claim 3: Transmission equipment for video signals comprising a transmitter provided with time axis expander for video signals and a receiver provided with time axis compressor for video signals received.

The special technical features are, in claim 1 the time axis expander, and in claim 2 the time axis compressor, which are corresponding technical features. Unity exists between claims 1 and 2. Claim 3 includes both special technical features and has unity with claims 1 and 2. The requirement for unity would still be met in the absence of the combination claim (claim 3).

10.30 Example 10

Claim 1: Conveyor belt with feature A.

Claim 2: Conveyor belt with feature B.

Claim 3: Conveyor belt with features A + B.

Feature A is a special technical feature and feature B is another unrelated special technical feature.

Unity exists between claims 1 and 3 or between claims 2 and 3, but not between claims 1 and 2.

10.31 Example 11

Claim 1: Control circuit A for a d.c. motor.

Claim 2: Control circuit B for a d.c. motor.

Claim 3: An apparatus including a d.c. motor with control circuit A.

Claim 4: An apparatus including a d.c. motor with control circuit B.

Control circuit A is a special technical feature and control circuit B is another unrelated special technical feature.

Unity exists between claims 1 and 3 or between claims 2 and 4, but not between claims 1 and 2 or 3 and 4.

10.32 Example 12

Claim 1: A display with features A + B.

Claim 2: A display according to claim 1 with additional feature C.

Claim 3: A display with features A + B with additional feature D.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is features A + B.

10.33 Example 13

- Claim 1: Filament A for a lamp.
- Claim 2: Lamp B having filament A.
- Claim 3: Searchlight provided with lamp B having filament A and a swivel arrangement C.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is the filament A.

10.34 Example 14

- Claim 1: A marking device for marking animals, comprising a disc-shaped element with a stem extending normally therefrom, the tip of which is designed to be driven through the skin of the animal to be marked, and a securing disk element to be fastened to the protruding tip of the stem on the other side of skin.
- Claim 2: An apparatus for applying the marking device of claim 1, constructed as a pneumatically actuated gun for driving the stem of the disc-shaped element through the skin, and provided with a supporting surface adapted for taking up a securing disc element, to be placed at the other side of the body portion in question of the animal to be marked.

The special technical feature in claim 1 is the marking device having a disc-shaped element with a stem and a securing disc element to be fastened to the tip of the stem. The corresponding special technical feature in claim 2 is the pneumatically actuated gun for driving the marking device and having a supporting surface for the securing disc element. Unity exists between claims 1 and 2.

10.35 Example 15

- Claim 1: Compound A.
- Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

10.36 Example 16

Claim 1: An insecticide composition comprising compound A (consisting of a₁, a₂...) and a carrier.

Claim 2: Compound a₁.

All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance.

There is nevertheless still unity between the subject matter of claims 1 and 2 provided a₁ has the insecticidal activity that is also the special technical feature for compound A in claim 1.

10.37 Example 17

- Claim 1: A chair with a lifting mechanism.
- Claim 2: A chair with a mechanical screw lifting mechanism.
- Claim 3: A chair with a hydraulic lifting mechanism.

Unity exists between claims 1-3. The special technical feature common to all the claims is the lifting mechanism. However, if any lifting mechanism is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

Markush Practice

10.38 Example 18: Common Structure

Claim 1: A compound of the formula:

$$R^3$$
 R^4
 R^2

wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R^2 - R^4 are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

10.39 Example 19: Common Structure:

Claim 1: A compound of the formula:

$$R_1$$
 $N = C - CH$ Z

wherein R_1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; Z is selected from the group consisting of oxygen (O), sulfur (S), imino (NH), and methylene (-CH2-).

The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

In this particular case the iminothioether group -N=C-SCH3 linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.40 Example 20: Common Structure

Claim 1: A compound of the formula:

$$N = C - CH$$

wherein R^1 is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).

The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mammalian tissue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents.

All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.41 Example 21: Common Structure

1 < **l** < 10

 $200 \ge n + m \ge 100$

$$X:$$
 H $-CH_2O Or$ CH_2O-

All of the above copolymers have in common a thermal degradation resistance property, due to the reduced number of free COOH radicals by esterification with X of the end COOH radicals which cause thermal degradation.

The chemical structures of the alternatives are considered to be technically closely interrelated to one another. A grouping in one claim is therefore allowed.

10.42 Example 22: Common Structure:

 $100 \ge n \ge 50$

$$X:$$
 H CH_2O- or H CH_2O-

The compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with $\langle H \rangle$ — CH_2O - has a thermal degradation resistant property, due to the reduced number of free COOH radicals which cause thermal degradation. In contrast, the compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with a vinyl compound containing a $CH_2 = CH - \langle C \rangle$ — CH_2O - moiety serves as a raw material for a setting resin when mixed with unsaturated monomer and cured (addition reaction).

All esters covered by the claim do not have a property or activity in common. For example, the product obtained through esterification with the " $CH_2 = CH$ " vinyl compound does not have a thermal degradation resistant property. The grouping in a single application is not allowed.

10.43 Example 23: No Common Structure

Claim 1: A herbicidal composition consisting essentially of an effective amount of the mixture of A 2,4-D(2,4-dichloro-phenoxy acetic acid) and B a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil (nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

The different components under B must be members of a recognized class of compounds. Consequently in the present case a unity objection would be raised because the members of B are not recognized as a class of compounds, but, in fact, represent a plurality of classes which may be identified as follows:

(a) inorganic salts:

copper sulfate

sodium chlorate ammonium sulfamate

(b) organic salts and carboxylic acids:

sodium trichloroacetate dichloropropionic acid

3-amino-2,5-dichlorobenzoic acid

(c) amides:

diphenamid

(d) nitriles:

ioxynil

(e) phenols:

dinoseb

(f) amines:

trifluralin

(g) heterocyclic:

simazine

10.44 Example 24

Claim 1: A pharmaceutical compound of the formula:

$$A-B-C-D-E$$

wherein:

A is selected from C_1 - C_{10} alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C_5 - C_7 heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C_1 - C_6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C_3 - C_8 ether or thioether:

C is selected from C_5 - C_8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C_4 - C_8 carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the various combinations. When determining the first invention, the content of the dependent claims will may be taken into account. Alternatively the first claimed invention—would may be considered to encompass the first mentioned structure for each variable, that is, A is C₁ alkyl, B is C₁ alkyl, C is a C₅ saturated heterocycle having one O heteroatom, D is C₁ alkyl, and E is a substituted phenyl.

10.45 Example 25

Claim 1: Catalyst for vapor phase oxidation of hydrocarbons, which consists of (X) or (X+a).

In this example (X) oxidizes RCH₃3 into RCH₂2OH and (X+a) oxidizes RCH₃3 further into RCOOH.

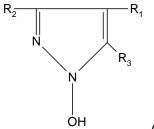
Both catalysts share a common component and a common activity as oxidation catalyst for RCH_33 . With (X+a) the oxidation is more complete and goes until the carboxylic acid is formed but the activity still remains the same.

A Markush grouping is acceptable in this case.

Intermediate/Final Product

10.46 Example 26

Claim 1:



(intermediate)

Claim 2:

$$R_2$$
 R_1
 R_3
 R_4
 R_5
(final product)

The chemical structures of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:

$$R_2$$
 R_3 R_3

Therefore, unity exists between claims 1 and 2.

10.47 Example 27

Claim 1:

$$R_1$$
 N
 N
 R_2
 R_3
 R_4
 R_4
 R_4
 R_4

Claim 2:

$$R_1$$
 N
 CH_2
 CH_2
 R_2
 CH_3
 R_4
 (II)

(II) is described as an intermediate to make (I). The closure mechanism is one well known in the art. Though the basic structures of compound (I) (final product) and compound (II) (intermediate) differ considerably, compound (II) is an open ring precursor to compound (I). Both compounds share a common essential structural element that is the linkage comprising the two phenyl rings and the triazole ring. The chemical structures of the two compounds are therefore considered to be technically closely interrelated.

The example therefore satisfies the requirement for unity of invention.

10.48 Example 28

Claim 1: Amorphous polymer A (intermediate).

Claim 2: Crystalline polymer A (final product).

In this example a film of the amorphous polymer A is stretched to make it crystalline.

Here unity exists because there is an intermediate final product relation in that amorphous polymer A is used as a starting product to prepare crystalline polymer A.

For purposes of further illustration, assume that the polymer A in this example is polyisoprene. Here the intermediate, amorphous polyisoprene, and the final product, crystalline polyisoprene, have the same chemical structure.

10.49 Example 29

Claim 1: Polymeric compound useful as fiber material identified by the following general formula:

[repeating unit (X)]

$$H \xrightarrow{\text{OCH}_2\text{CH}_2\text{O}} C \xrightarrow{\text{C}} C \xrightarrow{\text{OCH}_2\text{CH}_2\text{OH}} O C \xrightarrow{\text{O}} C$$

Claim 2: Compound identified by the following general formula:

(useful as intermediate for polymeric compound I)

$$H \xrightarrow{\text{OCH}_2\text{CH}_2\text{O}} C \xrightarrow{\text{C}} C \xrightarrow{\text{OCH}_2\text{CH}_2\text{OH}} O C \xrightarrow{\text{C}} O C$$

(primary condensation product)

The two inventions are in an intermediate and final product relationship.

Substance (II) is a raw material for substance (I).

Meanwhile, both compounds share an essential structural element (repeating unit (X)) and are technically closely interrelated. The intermediate and final products therefore satisfy the requirements for unity.

10.50 Example 30

Claim 1: Novel compound having structure A (lintermediate).

Claim 2: Product prepared by reacting A with a substance X (Final Pproduct).

(see below for further details)

10.51 Example 31

Claim 1: Reaction product of A and B (lintermediate).

Claim 2: Product prepared by reacting the reaction product of A and B with substances X and Y (Final Pproduct).

In examples 30 and 31 the chemical structure(s) of the intermediate and/or the final product is not known. In (30) the structure of the product of claim 2 (the final product) is not known. In (31) the structures of the products of claim 1 (the intermediate) and claim 2 (the final product) are unknown.

Unity exists if there is evidence that would lead one to conclude that the characteristic of the final product which is the inventive feature in the case is due to the intermediate. For example, the purpose for using the intermediates in Examples 30 er and 31 is to modify certain properties of the final product. The evidence may be in the form of test data in the specification showing the effect of the intermediate on the final product. If no such evidence exists then there is no unity on the basis of an intermediate-final product relationship.

Biotechnological Inventions

10.52 Example 32: Multiple Structurally and Functionally Unrelated Polynucleotides

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the claimed polynucleotides are 500 bp cDNAs obtained from a human liver cDNA library. The polynucleotides are structurally different and can be used as probes to obtain full-length DNAs, although there is no description of the function or biological activity of the corresponding proteins. Furthermore, the polynucleotides claimed are not homologous to each other.

There is no prior art available. A human liver cDNA library had not been established before.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the polynucleotides SEQ ID NOs: 1-10 share a common property or activity. While each sequence may serve as a probe to isolate its own respective full length DNA, due to the lack of homology between SEQ ID NOs: 1-10, a probe derived from SEQ ID NO: 1 cannot be used to isolate SEQ ID NOs: 2-10, respectively.

Moreover, since the polynucleotides are not homologous to each other, they fail to share a common structure i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. Therefore, the 10 polynucleotide molecules do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments are derived from the same source (human liver) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention (a priori).

One possible grouping would be:

Inventions 1-10: Polynucleotides having SEQ ID NOs: 1-10.

10.53 Example 33: Multiple Structurally and Functionally Related Polynucleotides

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The facts are the same as Example 32 except that the claimed polynucleotides all share a significant structural element and their corresponding mRNAs are expressed only in the hepatocytes of patients with disease Y. The corresponding mRNAs are not expressed in the hepatocytes of healthy individuals.

There is no prior art available. The shared structural element had not been identified before, nor had any link been established between genes expressing mRNA containing that structural element and patients afflicted with disease Y.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description discloses that SEQ ID NOs:1-10 share a common property, that is, expression of an mRNA present only in patients afflicted with disease Y. Moreover, SEQ ID NOs: 1-10 share a significant structural element that is essential to the common property, i.e., a probe comprising the shared structural element can detect the mRNA of patients afflicted with disease Y. Since both of these requirements are met, the group of polynucleotide molecules claimed meets the requirement of unity of invention (a priori).

10.54 Example 34: Functionally Unrelated Single Nucleotide Polymorphisms (SNPs)

Claim 1: An isolated nucleic acid molecule comprising SEQ ID NO: 1 with a single polymorphic change at one of the positions as shown below:

Polymorphism	Position	Change from SEQ ID NO: 1 to:
1	10	G
2	27	Α
3	157	С
4	234	Τ
5	1528	G
6	3498	С
7	13524	Τ
8	14692	A -

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

According to the description, SEQ ID NO: 1 is 22,930 nucleotides in length. The SNPs 1-8 are not characterized, that is, no common property or activity has been disclosed.

SEQ ID NO: 1 has been described in the prior art but no specific function has been identified.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the SNPs 1-8 share a common property or activity. The fact that all point mutations are within a defined sequence (SEQ ID NO: 1) is not sufficient to establish unity of invention since SEQ ID NO: 1 has already been described in the prior art, and no functional relationship exists among the different SNPs claimed. For this reason, the SNPs of claim 1 lack unity of invention.

One possible grouping would be:

Inventions 1-8: SNPs 1-8.

10.55 Example 35: Molecules Which Share a Common Function not Linked to a Common Structure

Claim 1: A fusion protein comprising carrier protein X linked to a polypeptide having SEQ ID NO 1, 2, or 3.

The description discloses that carrier protein X is 1000 amino acids in length and functions to increase the stability of the fusion proteins in the blood stream. SEQ ID NOs: 1, 2, and 3 are small epitopes (10-20 residues in length) isolated from different antigenic regions of E.coli. SEQ ID NOs: 1, 2, and 3 do not share any significant common structure.

Both the structure of protein X and its function as a carrier protein are known in the prior art. Fusion proteins that generate an antigenic response to E. coli are known in the prior art.

The fusion proteins of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the only common structure shared by the fusion proteins is carrier protein X. The fusion proteins share a common property, i.e., generation of an antibody response specific for *E. coli*. However, immunization with the carrier protein alone does not result in the common property; SEQ ID NO: 1, 2, or 3 is required for this property.

No special technical feature exists among the three fusion proteins. The fact that all the fusion proteins have a common property is not sufficient to establish unity of invention because (1) SEQ ID NOs: 1, 2, and 3, which impart the common property, do not share a significant structural element, (2) the common structure, carrier protein X, does not impart the common property, and (3) fusion proteins that generate an antigenic response specific for *E. coli* are known in the prior art.

One possible grouping would be:

Invention 1: Fusion protein comprising carrier protein X and SEQ ID NO: 1.

Invention 2: Fusion protein comprising carrier protein X and SEQ ID NO: 2.

Invention 3: Fusion protein comprising carrier protein X and SEQ ID NO: 3.

10.56 Example 36: Multiple Nucleic Acid Molecules Which Share Common Structure and Encode Proteins with Common Property

Claim 1: An isolated nucleic acid selected from SEQ ID NO: 1, 2, or 3.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the three nucleic acids encode dehydrogenases that include a conserved sequence motif defining the catalytic site and the dehydrogenase function of these proteins. The three nucleic acids were isolated from three different sources (mouse, rat, and human). The description clearly shows that these three nucleic acids are homologous based upon their overall sequence similarity (85-95% identity) at both the nucleotide and amino acid sequence levels.

The prior art describes a nucleic acid molecule isolated from monkeys, which has high sequence similarity (e.g., 90%) to SEQ ID NO: 1. The monkey nucleic acid encodes a dehydrogenase that includes the catalytic site defined by the conserved motif.

The nucleic acids of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

Rule 13.2 requires that the technical feature shared between the inventions defines a contribution over the prior art.

A same or corresponding technical feature shared among the claimed nucleic acid molecules resides in their common property (encoding dehydrogenases) and their shared structural element that is essential to the common property (the conserved motif). However, a nucleic acid molecule which encodes a dehydrogenase and contains the shared structural element has already been isolated from a different source (monkeys). Thus, the technical feature is not special because the functional and structural similarity between the claimed molecules cannot form the contribution that the group of inventions as a whole makes over the prior art. Therefore, unity of invention is lacking (a posteriori).

On the other hand, if the only prior art available disclosed a nucleic acid molecule encoding a dehydrogenase that lacked the catalytic site defined by the conserved sequence motif, the technical feature would be special and SEQ ID NOs: 1, 2, and 3 would have unity of invention.

A possible grouping would be:

Invention 1: Nucleic acid of SEQ ID NO: 1
Invention 2: Nucleic acid of SEQ ID NO: 2
Invention 3: Nucleic acid of SEQ ID NO: 3

10.57 Example 37: DNA Encoding Receptors with Partial Structural Identity and Asserted Common Property

Claim 1: A polynucleotide encoding a guanosine triphosphate-binding protein coupled receptor (GPCR) comprising a nucleotide sequence selected from the group consisting of the odd-numbered SEQ ID NOs from SEQ ID NO: 1 to SEQ ID NO: 2069.

The description identifies a conserved sequence of 15 amino acid residues found in several known GPCR molecules that is asserted to be essential to the GPCR function. A consensus polynucleotide sequence encoding the conserved amino acid sequence was generated. A database containing human genome sequences was searched using the consensus polynucleotide sequence. Using this system, 1035 polynucleotide sequences were identified, which are asserted to encode GPCR molecules that include the conserved sequence.

The prior art discloses human GPCR molecules that contain the conserved sequence of 15 amino acid residues, as well as the polynucleotide sequences that encode the conserved 15 amino acid sequence.

The common technical feature among the 1035 polynucleotide sequences is the consensus polynucleotide sequence that encodes the common sequence of 15 amino acid residues. This technical feature is not special because the consensus polynucleotide sequence was known and therefore cannot form the contribution that the group of inventions as a whole makes over the prior art. Consequently, the 1035 different polynucleotides lack unity of invention (*a posteriori*).

One possible grouping would be:

Inventions 1-1035: Polynucleotides based on SEQ ID NOs: 1-2070-2069 (odd-numbers)

If the description did not assert, or it was not readily apparent, that the conserved sequence of 15 amino acid residues was essential to the GPCR function, unity of invention could be lacking in the absence of any relevant prior art.

On the other hand, given the assertion in the description, in the absence of the prior art in the example, the groups would have had unity of invention.

10.58 Example 38: Method of Screening and Compounds Identified by the Method

Claim 1: A method to identify compounds that are antagonists of receptor R comprising the steps of contacting cells expressing on their outer membrane receptor R with its natural ligand; observing the binding of the ligand; contacting said cells bound to said ligand with a candidate compound selected from a library of compounds; and observing any change in the binding of the ligand.

Claim 2: Compound X, having formula 1.

Claim 3: Compound Y, having formula 2.

Claim 4: Compound Z, having formula 3.

Receptor R and its natural ligand are proposed as a drug target. Compounds that antagonise receptor R are proposed to have physiological effects that may be useful in therapeutic treatment. The aim is to identify lead compounds as a basis for further screening and testing of combinatorial libraries. A library is described as providing many possible structurally different compounds. Examples show that the method of claim 1 can be used to identify compounds affecting the physiological effect of binding of the natural ligand to the receptor. Only compounds X, Y and Z were shown to have such effects, but they do not appear to share a significant structural element. The description is silent with regard to the both the relationship between the structure and activity of the claimed compounds and the relationship between the structure of receptor R and the structure of the compounds.

Receptor R, its biological function, and its natural ligand are known in the prior art. No compounds that function as antagonists of receptor R are known.

The technical feature of method claim 1 resides in the step of observing the effect of the candidate compounds on ligand binding in a screening assay. Neither the same nor a corresponding special technical feature is present in any of compounds X, Y, or Z. No manufacturing relationship exists between the screening method and the claimed compounds. Further, the screening method is not a method of using claimed compounds X, Y, and Z. In the absence of any teaching as to the structure required for a compound to act as a receptor R antagonist, there is no single general concept that links the method to the claimed compounds. Thus, unity of invention is lacking (a priori).

Compounds X, Y, and Z would be regarded as having the same or corresponding technical feature if they had a common property or activity, and shared a significant structural element that is essential to the common property or activity. While compounds X, Y, and Z do share the common property of antagonizing receptor R, there is no teaching as to a shared significant structural element, and hence, there is no disclosure of the same or corresponding technical feature.

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)

Invention 2: Compound X (claim 2)

Invention 3: Compound Y (claim 3)
Invention 4: Compound Z (claim 4)

10.59 Example 39: Protein and its Encoding DNA

Claim 1: Isolated protein X having SEQ ID NO: 1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO: 1.

There is no prior art.

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

If an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X, some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity. Examples of such a claim follow:

Isolated DNA molecule encoding protein X, or a DNA fragment thereof.

Isolated DNA molecule having SEQ ID NO: 2, or DNA molecules which hybridise to SEQ ID NO: 2 under stringent conditions.

If prior art existed teaching either protein X or the DNA encoding protein X, some Authorities might find that the same or corresponding technical feature did not make a contribution over the prior art, that is, was not a special technical feature, and therefore unity was lacking (a posteriori).

Process at the International Search Stage

Invitation to Pay Additional Fees

Article 17(3)(a); Rules 16, 40.1, 40.2, 40.3, 42

- 10.60 After deciding that lack of unity exists, except in the circumstances described in paragraphs 10.64 and 10.65, the International Searching Authority informs the applicant of the lack of unity of invention by a communication, preceding (but see paragraph 10.61 below) the issuance of the international search report and written opinion of the International Searching Authority, which contains an invitation to pay additional fees (Form PCT/ISA/206). This invitation:
- (i) specifies the reasons (see paragraph 10.63) for which the international application is not considered as complying with the requirement of unity of invention:
- (ii) identifies the separate inventions and indicates the number of additional search fees and the amount to be paid.: and
- (iii) invites the applicant to pay, where applicable, the protest fee (see paragraphs 10.6610.60 to 10.70).

The International Searching Authority cannot consider the application withdrawn for lack of unity of invention, nor invite the applicant to amend the claims, but informs the applicant that, if the international search report is to be drawn up in respect of those inventions present other than the first mentioned, then the additional fees (and the protest fee, where applicable) must be paid within a stipulated period one month from the date of the invitation.

If the applicant wishes to pay the additional fees under protest and a protest fee is payable (see paragraphs 10.66 to 10.70), the International Searching Authority also invites the applicant to pay any such fee within one month from the date of the invitation.

- If preferred, the said invitation may be already accompanied by a notification of the 10.61 result of a partial international search drawn up for those parts of the international application which relate to what is to be considered as the "first" invention. The result of the partial international search will be very useful for the applicant in deciding whether additional search fees should be paid so that further parts of the international application would be subjected to the international search. The invention(s) or group(s) of inventions, other than the one first mentioned in the claims, will be searched, subject to paragraphs 10.64 and 10.65, only if the applicant pays the additional fees. Thus, whether the lack of unity of invention is directly evident a priori or becomes apparent a posteriori, the examiner, may proceed in one of two ways: he may immediately inform the applicant of his finding and invite him to pay additional search fees and any protest fee, where applicable (with Form PCT/ISA/206) and search or continue to search the invention first mentioned in the claims ("main invention"); or alternatively, he may carry out the search on the "main invention" and draw up a partial international search report which will be sent together with the invitation to pay additional search fees and any protest fee, where applicable (with Form PCT/ISA/206).
- 10.62 Since these payments must take place within a period to be set by the International Searching Authority so as to enable the observation of the time limit for establishing the international search report set by Rule 42, the applicant is given one month to make these payments before any further search will be made, the International Searching Authority should endeavor to ensure that international searches be made as early as possible after the receipt of the search copy so as to enable compliance with the time limit for establishing the international search report set by Rule 42. The International Searching Authority finally draws up the international search report and written opinion on those parts of the international application which relate to inventions in respect of which the search fee and any additional search fee have been paid. The international search report (see paragraph 16.32) and written opinion (see paragraphs 17.38 and 17.39) identify the separate inventions or groups of inventions forming unity and indicate those parts of the international application for which a search has been made. If no additional search fee has been paid, the international search report and written opinion contain only the references relating to the invention first mentioned in the claims.

Rule 40.1

10.63 In the invitation to pay additional fees, the International Searching Authority sets out a logically presented, technical reasoning containing the basic considerations behind the finding of lack of unity.

Search of Additional Inventions Without Payment of Fees

- 10.64 If little or no additional search effort is required, reasons of economy *may* make it advisable for the examiner, while making the search for the main invention, to search at the same time, despite the nonpayment of additional fees, one or more additional inventions in the classification units consulted for the main invention. The international search for such additional inventions will then have to be completed in any further classification units which may be relevant, when the additional search fees have been paid. This situation may occur when the lack of unity of invention is found either *a priori* or *a posteriori*.
- 10.65 When the examiner finds lack of unity of invention, normally, the applicant is invited to pay fees for the search of additional inventions. In exceptional circumstances, however, the examiner may be able to establish both an international search and a written opinion covering more than one invention with negligible additional work, in particular, when the inventions are conceptually very close. In those cases, the examiner may decide to complete the international search and written opinion for the additional invention(s) together with that for the invention first mentioned. In considering the amount of work involved, the

examiner should take into account the time taken to create the written opinion as well as that needed to perform the search, since even when the analysis involved as regards the search is negligible, the opposite may be the case for the written opinion of the International Searching Authority and therefore justify requesting the additional fees. If it is considered that the total additional work does not justify requesting additional fees, all results are included in the international search report without inviting the applicant to pay an additional search fee in respect of the additional inventions searched, but stating the finding of lack of unity of invention.

Protest Procedure

Rule 40.2(c), (e)

10.66 The applicant may protest the allegation of lack of unity of invention, or that the number of required additional fees is excessive and request a refund of the additional fee(s)s paid. If, and to the extent that, the International Searching Authority finds the protest justified, the fee(s)s are refunded. (The additional search fees must be paid for any protest to be considered. The International Searching Authority may require a protest fee to be paid in order for the protest to be considered (see paragraph 10.69).

Rule 40.2(c)

10.67 Protest of allegation of lack of unityThe protest is in the form of a reasoned statement accompanying payment of the additional fee, explaining why the applicant believes that the requirements of unity of invention are fulfilled and fully taking into account the reasons indicated in the invitation to pay additional fees issued by the International Searching Authority.

Rule 40.2(c), (d); Section 403

10.68 The protest is examined by a three-member board or other special instance of the International Searching Authority or any competent higher authority a review body constituted in the framework of the International Searching Authority, and a decision taken on it. The procedure is determined by each International Searching Authority, although the review body must not be limited to the person who made the decision which is the subject of the protest. Some Authorities may review the protest in two stages, with a formal board review body being convened only if a preliminary review of the protest considers reveals that the protest is not entirely justified. To the extent that the applicant's protest is found to be justified, the additional fees is are totally or partly reimbursed. At the request of the applicant, the texts of both the protest and the decision on it are notified to the designated Offices by the International Bureau together with the international search report (see paragraph 10.70).

Rule 40.2(c), to (e)

Where the applicant has paid an additional fee under protest, the International 10.69 Searching Authority may require the applicant also to pay a fee for the examination of the protest ("protest fee"). Details of the protest fee, if any, charged by the International Searching Authorities appear in Annex D of the PCT Applicant's Guide, Volume I Annex D. -Introduction to the International Phase. If a protest fee is chargeable by the International Searching Authority, it is only required in a particular case after a prior review of the justification for the invitation to pay additional search fees. The review should not be made by the examiner who made the finding alone. If the invitation to pay additional fees is maintained, the applicant is invited to pay the protest fee within one month from the date of the notification to the applicant of the result of the review. The notification of the result of the review, if negative, gives a technical reasoning of that result. If the protest fee is not paid within one month from the date of the invitation to pay additional fees, the protest is considered not to have been madewithdrawn. The protest fee is refunded to the applicant under Rule 40.2(e) only where the review body three-member board, special instance or higher authority finds that the protest was entirely justified. This means that, where the protest requests the reimbursement of some but not all of the additional search fees paid and all of those search fees referred to in the protest are refunded by the review body, a refund of

the protest fee is also due. For example, the applicant pays four additional search fees, but in the protest only requests the refund of two of these. If both of these fees are refunded, then the protest was entirely justified and a refund of the protest fee is also due. The applicant may, on the payment of the protest fee, supplement the reasoned statement which accompanied the protest, taking into consideration the result of the review.

Rule 40.2(c); Section 502

10.70 Where the applicant paid additional search fee(s)fees under protest, he is informed promptly (using Form PCT/ISA/212 may be used for that purpose) of any decision about the compliance with the requirement of unity of invention. At the same time the International Searching Authority transmits to the International Bureau a copy of the protest and of the decision thereon as well as any request by the applicant to forward the texts of both the protest and the decision thereon to the designated Offices.

Process at the International Preliminary Examination Stage

Article 34(3)(a) to (c); Rule 68

- 10.71 The procedure before the International Preliminary Examining Authority regarding lack of unity of invention is governed by Article 34(3)(a) to (c) and Rule 68 (see also Rule 70.13). This procedure is more fully explained in paragraphs 10.74 to 10.82. It should be noted that in most instances lack of unity of invention will have been noted and reported upon by the International Searching Authority, which will have drawn up an international search report and written opinion based on those parts of the international application relating to the invention, or unified linked group of inventions, first mentioned in the claims ("main invention"), unless the applicant has paid additional fees.
- 10.72 If the applicant has not availed himself of the opportunity to have the international search report issued on at least some of the other inventions, this must be taken as an indication that the applicant is prepared for the international application to proceed on the basis that it relates to the invention first mentioned in the claims as originally contained in the international application as filed.
- 10.73 However, whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner during international preliminary examination. In his consideration, he should take into account all the documents cited in the international search report and any additional documents considered to be relevant.

Rule 68.2, 68.3

10.74 Where the examiner finds a lack of unity of invention, a communication may, at the option of the examiner (see paragraph 10.76), be sent to the applicant, using Form PCT/IPEA/405, informing him why there is a lack of unity of invention and inviting him within a period stated in the invitation (the period may be between one and two monthsone month from the date of the invitation), either to restrict the claims or to pay an additional fee for each additional invention claimed. Where such a communication is sent, at least one possible restriction, which would avoid the objection of lack of unity of invention, is indicated by the examiner. In the invitation to pay additional fees, the examiner sets out a logically presented, technical reasoning containing the basic considerations behind the finding of lack of unity in accordance with these Guidelines. Where a protest fee is payable if the applicant wishes to pay the additional fees under protest (see paragraphs 10.78 to 10.82), the International Preliminary Examining Authority also invites the applicant to pay any such fee within one month from the date of the invitation.

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

10.75 If the applicant does not comply with the invitation (by not paying the additional fees or by not restricting the claims either sufficiently or at all), the international preliminary examination report is established on those parts of the international application which relate to what appears to be the "main invention" and the examiner indicates the relevant facts in

such report. In cases of doubt as to which is the main invention, the invention first mentioned in the claims is considered the main invention.

Rule 68.1, 68.3(c) to (e); Section 603

10.76 However, there are cases of lack of unity of invention where, compared with the procedure of inviting the applicant to restrict the claims or to pay additional fees (Rule 68.2), no or little additional effort is involved in establishing the international preliminary examination report for the entire international application. Then, reasons of economy may make it advisable for the examiner to avail himself of the option referred to in Rule 68.1 by choosing not to invite the applicant to restrict the claims or to pay additional fees. In this situation, he carries out his preliminary examination and establishes the international preliminary examination report on the entire international application, but indicates, when establishing the report, his opinion that the requirement of unity of invention is not fulfilled and the reasons therefore.

Article 34(3)(c)

10.77 If the applicant timely complies with the invitation to pay additional fees even under protest, or to restrict the claims, the examiner carries out international preliminary examination on those claimed inventions for which additional fees have been paid or to which the claims have been restricted. It should be noted that "the national law of any elected State may provide that, where its national Office finds the invitation of the IPEA justified, those parts of the international application which do not relate to the main invention shall, as far as effects in that State are concerned, be considered withdrawn unless a special fee is paid by the applicant to that Office" (Article 34(3)(bc)).

Protest Procedure

40.78 Where the applicant has paid an additional fee under protest, the International Preliminary Examining Authority may require the applicant also to pay a fee for the examination of the protest ("protest fee"). Details of the protest fee, if any, charged by the International Preliminary Examining Authorities appear in Annex E of the PCT Applicant's Guide, Volume I - Introduction to the International Phase. If a protest fee is chargeable by the International Preliminary Examining Authority, it is only required in a particular case after a prior review of the justification for the invitation to pay additional fees. The review should not be made by the examiner who made the finding alone. If the invitation to pay additional fees is maintained, the applicant is invited to pay the protest fee within one month from the date of the notification to the applicant of the result of the review. The notification of the result of the review, if negative, gives a technical reasoning of that result. If the protest fee is not paid, the protest is considered withdrawn. The protest fee is refunded to the applicant under Rule 68.3(e) where the three-member board, special instance or higher authority finds that the protest was entirely justified. The applicant may, on the payment of the protest fee, supplement the reasoned statement which accompanied the protest, taking into consideration the result of the review

Rule 68.3(c)

10.78 The applicant may protest the allegation of lack of unity of invention or that the number of required additional fees is excessive and request a refund of the additional fees paid. If, and to the extent that, the International Preliminary Examining Authority finds the protest justified, the fees are refunded. (The additional examination fees must be paid for any protest to be considered.) The International Preliminary Examining Authority may require a protest fee to be paid in order for the protest to be considered (see paragraph 10.81).

Rule 68.3(c)

10.79 The protest is in the form of a reasoned statement accompanying payment of the additional fee, explaining why the applicant believes that the requirements of unity of invention are fulfilled and fully taking into account the reasons indicated in the invitation to pay additional fees issued by the International Preliminary Examining Authority.

Rule 68.3(c), (d); Section 403

10.79 10.80 The protest is examined by a review body constituted in the framework of the International Preliminary Examining Authority, and a decision taken on it. The procedure is determined by each International Preliminary Examining Authority, although the review body must not be limited to the person who made the decision which is the subject of the protest. Some Authorities may review the protest in two stages, with a formal board review body being convened only if a preliminary review of the protest considers reveals that the protest is not entirely justified. To the extent that the applicant's protest is found to be justified, the additional fees are totally or partly reimbursed. At the request of the applicant, the texts of both the protest and the decision on it are notified to the elected Offices by the International Bureau as an annex to item accompanying the international preliminary examination report (see paragraph 10.82).

Rule 68.3(e)

<u>40.80</u>10.81 Details of the protest fee, if any, charged by the International Preliminary Examining Authorities appear in the PCT Applicant's Guide, Volume I, Annex E. If, where it is due, the protest fee is not paid within one month from the date of the invitation to pay, the protest is considered not to have been made. The protest fee is only refunded to the applicant under Rule 68.3(e) where the review body finds that the protest was entirely justified (the same principles are applied in the assessment as to whether the refund is due as are applied at the stage of international search under Rule 40, see paragraph 10.69).

Rule 68.3(c); Section 603

10.81 Where the applicant paid additional examination fees under protest, he is informed promptly (using Form PCT/IPEA/420) of any decision about compliance with the requirement of unity of invention. At the same time the International Preliminary Examining Authority transmits to the International Bureau a copy of the protest and of the decision thereon as well as any request by the applicant to forward the texts of the protest and the decision to elected Offices.

Process at the Supplementary International Search Stage

Rule 45bis.6

10.83 Contrary to the case for the main international search, there is no opportunity to pay additional fees for search of further inventions at the supplementary international search stage. Consequently, subject to the possibility of search of additional inventions without payment of fees where little additional search effort is required (as indicated in paragraphs 10.64 and 10.65 with respect to the main international search), the supplementary international search report should be established immediately on the main invention only (see paragraph 10.86 for consideration of what is the main invention).

Rule 45bis.6(a), (b)

The Authority specified for supplementary international search may make its own assessment as to unity of invention, but it should take into account the opinion of the main International Searching Authority included in the international search report as well as any protest by the applicant or decision by the International Searching Authority in relation to such a process protest which is received prior to the start of the supplementary international search.

10.82 10.85 If the examiner considers that there is a lack of unity of invention, this should be explained in Box No. III of the supplementary international search report. If the examiner agrees with the assessment in the main international search report, this can be reported by simply referring to the international search report. On the other hand, if the examiner forms a different point of view, or agrees with a revised view on unity of invention in a decision relating to a protest (which will usually not appear in the original international search report, but will only be available later as a separate later document), the reasoning should be set out in full so that it is easily understood by both the applicant and third parties.

Rules 45bis.1(d), 45bis.6(a), (f)

The main invention will normally be the invention first mentioned in the claims, but the examiner should use appropriate discretion in selecting the invention to be searched where the first mentioned invention is one for which no search report would be established (due to lack of clarity, subject matter excluded from the search or for any other reason), or else where the applicant has requested that the supplementary search should be limited to one of the inventions other than the first identified by the International Searching Authority responsible for the main international search (for example, because the first invention has been shown by the main international search to be so completely anticipated that it is clear that no patent could be granted for that invention).

Review of Opinion

- 10.87 The normal protest procedure (see paragraphs 10.66 to 10.70) does not apply to requests for supplementary international search. However, the applicant may, within one month of the date of notification of the supplementary international search report, request the Authority to review the examiner's opinion on unity of invention. This request may be subject to a review fee. The results of the review are promptly notified to the applicant using Form PCT/SISA/503. The same form can be used to indicate that the request for review is considered not to have been made because the review fee has not been paid within 1 month from the date on which the examiner's opinion was notified to the applicant.
- 10.88 If the examiner's opinion is found to be at least partly unjustified, the Authority should issue a corrected revised supplementary international search report, stating the revised view on unity of invention and, where appropriate, including the search results for all claims which should have been included. If the opinion was entirely unjustified, the applicant should also have any review fee refunded.

Chapter 11 Prior Art

Prior Art Generally

Article 33(2); Rule 33.1

11.01 The prior art for the purposes of assessing the novelty (see Chapter 12) and inventive step (whether or not the invention is obvious; see Chapter 13) of an invention is defined as "everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations)" before the "relevant date." The scope of this definition should be noted. There are no restrictions whatsoever as to the geographical location where, or the language or manner (including written disclosure posted on the Internet or an on-line database) in which, the relevant information contained in the written disclosure was made available to the public. There are no restrictions as to the age of the prior art document (whether it is 100 years old or was published one day prior to the "relevant date") so long as the document was made available to the public before the "relevant date." If the applicant makes an admission, the subject matter mentioned in the admission (for example, a figure in an international application labeled as "prior art") may constitute prior art. The presumption that the admission constitutes prior art may be rebutted by the applicant.

Date of Disclosure

Rules 33.1, 43bis.1, 64.1

11.02 It should be noted that the definition of relevant prior art for purposes of international search report is different from the definition of relevant prior art for other purposes, including the written opinion established by the International Searching Authority because "relevant date" is defined differently for international search report purposes and for written opinion and international preliminary examination purposes.

Relevant Date for International Search Report Purposes

11.03 Rule 33.1 makes it clear that potentially relevant disclosures should be included in the international search report "provided that the making available to the public occurred prior to the international filing date." Rule 33.1 defines "relevant date" as the international filing date of the international application. This ensures that the international search report provides information which will be complete even if national authorities disagree with the examiner's opinion on the validity of the priority claim.

Relevant Date for Written Opinion and International Preliminary Examination Purposes

Rule 2.4(a)

- 11.04 For the purposes of the written opinion and international preliminary examination, Rule 64.1 defines the relevant date as:
- (i) <u>subject to items</u> (ii) <u>and</u> (iii), the international filing date of the international application under international preliminary examination (or, in conjunction with Rule 43*bis*.1(b), for which a written opinion is being established by the International Searching Authority); or
- (ii) where the international application claims the priority of an earlier application and has an international filing date which is within the priority period (12 months from the filing date), the filing date of such earlier application, unless the International Authority considers that the priority claim is not valid; where that international application validly claims the priority of an earlier application, the filing date of such earlier application.
- (iii) where the international application claims the priority of an earlier application and has an international filing date which is later than the date on which the priority period expired but within the period of two months from that date, the filing date of such earlier application, unless the International Authority considers that the priority claim is not valid for

reasons other than the fact that the international application has an international filing date which is later than the date on which the priority period expired.

11.05 Clearly, when a potentially relevant document has been published between a claimed priority date of the application and its international filing date, the examiner is required to consider whether the claimed priority date is valid for the purposes of determining the "relevant date" of the claims in the international application. Note: If there is time left for the applicant to perfect, correct or add a priority claim but there is insufficient time for the examiner to make a proper determination as to whether the priority claim is valid, due to the need to issue a timely written opinion by the International Searching Authority, the "relevant date" for the purposes of the written opinion will be based on the claimed priority date. (See paragraphs 6.17 and 17.29(b)).

Documents Casting Doubt on Priority Claim Made in the International Application

11.06 Documents showing that a priority claim in the international application might not be justified (for example, an earlier application or patent resulting therefrom, by the same applicant, indicating that the application from which priority is claimed may not be the first application for the invention concerned) should be mentioned in the international search report and explained in the relevant portion of the written opinion. No special search is normally made by the International Searching Authority to determine whether the priority claim made in the international application is justified, except when there is a special reason to do so, for example, when the priority application is a "continuation-in-part" of an earlier application from which no priority is claimed; also sometimes the fact that the country of residence of the applicant is different from the country of the priority application may be an indication of possible lack of first filing, justifying a certain extension of the international search.

Documents Not Within the Prior Art Which May Nevertheless Be Relevant

Later Published Patent Applications (for Purposes of the International Search Report)

Rule 33.1(c)

11.07 Furthermore, the international search report includes published patent applications or patents whose publication date is the same as, or later than, but whose filing date, or, where applicable, claimed priority date, is earlier than the international filing date of the international application searched, and which would constitute relevant prior art for the purposes of Article 15(2) had they been published prior to the international filing date.

Later Published Patent Applications (for Purposes of International Preliminary Examination)

Rule 64.3

- 11.08 These earlier filed but later published patent applications or patents are not considered part of the prior art for the purpose of international preliminary examination as to novelty and inventive step. Nevertheless, the written opinion of the International Searching Authority and the preliminary examination report must draw attention to such published applications or patents in the manner provided for in Rule 70.10 (see paragraph 17.45) since they may be relevant to the determination of novelty and inventive step by designated or elected Offices.
- 11.09 Rule 70.10 provides that any published application or any patent referred to in the international preliminary examination report by virtue of Rule 64.3 is mentioned as such and is accompanied by an indication of its date of publication, of its filing date, and its claimed priority date (if any). In respect of the priority date of any such document, the report may indicate that, in the opinion of the International Preliminary Examining Authority, such date has not been validly claimed.

Copending Applications, Including Those Filed on the Same Date

11.10 The PCT does not deal explicitly with the case of co-pending international applications of the same date. However, it is an accepted principle in most patent granting systems that two patents shall not be granted to the same applicant for one invention. It is permissible to allow an applicant to proceed with two international applications having the same description where the claims are quite distinct in scope and directed to different subject matter. However, in the rare case in which there are two or more international applications from the same applicant designating the same State or States and the claims of those applications have the same priority date and relate to the same invention (even though they may not necessarily claim that invention in identical terms), each conflicting application should (as long as it has already been published) be cited in the international search report and identified with a "L" category symbol as raising possible double patenting issues. A notification, to the applicant alone, is given in the case where his international application designates a State in which he proceeds with a national application having the same priority date and relating to the same invention as the said international application, if the examiner is aware of this situation. However, no such notification should be given where two applications (international or otherwise) of the same priority date and relating to the same invention are received from two different applicants.

Documents Relevant to Understanding the Invention

Section 507(e)

11.11 Certain other situations may occur in which a document published on or after the international filing date is relevant; examples are a later document containing the principle or theory underlying the invention, which may be useful for a better understanding of the invention, or a later document showing that the reasoning or the facts underlying the invention are incorrect. The international search is not extended for this purpose, but documents of this nature known to the search examiner may be selected for citation in the international search report. Such documents are cited in the international search report and their relevance explained in the written opinion.

Form of Disclosure

Availability of Written Disclosures to the Public

Rules 33.1(c), 64.3, 70.10

11.12 A written disclosure, that is, a document, is regarded as made available to the public if, at the relevant date (see paragraphs 11.02 to 11.05), it was possible for members of the public to gain access to the content of the document and to acquire possession of the content of the document, and there was no bar of confidentiality restricting the use or dissemination of knowledge gained thereby. Whether the absence of an index or a catalogue of the document constitutes inaccessibility of the content of the document to the public is determined in accordance with the above principle. Where the document only provides the month or the year, but not the specific date, which the document was made available to the public, the content of the document is presumed to have been made available to the public on the last day of that month or that year, respectively, unless evidence is provided to prove otherwise.

Disclosure on the Internet

11.13 Prior art disclosure on the Internet or on an on-line database is considered in the same manner as other forms of written disclosure. Information disclosed on the Internet or on-line database are considered to be publicly available as of the date the disclosure was publicly posted. When citing an Internet disclosure (a web page), problems may arise in establishing the date of publication and whether or not the disclosure has been modified over time. When establishing the publication date of a web page, it is important to distinguish between two types of Internet disclosure, viz: those made on the web sites of trusted publishers and those made on web sites of unknown reliability.

Disclosure Made on the Web Sites of Trusted Publishers

- 11.14 Examples of these are on-line scientific journals (which make available the contents of a paper journal on-line, or may be uniquely on-line publications). The web sites of newspapers, periodicals, television and radio stations will usually fall into this category as well. This type of Internet disclosure gives the publication date of the disclosure which, in the absence of evidence to the contrary, should be taken at face value. The examiner should cite the Internet disclosure in the Linternational search report and use it in the written opinion of the International Searching Authority and in preliminary examination accordingly. The onus is on the applicant to prove otherwise.
- 11.15 It may happen that the publication date is not sufficiently identified to know if it is published in time to be considered to be state of the art according to Rule 64.1(b) (that is, it is not clear if the disclosure occurred before or after the valid priority date). This may happen, for example, where only the month or year of publication is given and this is the same as the month or year of the valid priority of the international application. In these cases, the Authority may need to make enquiries with the owner of the web site in order to establish the publication date to a sufficient degree of accuracy to know if it is relevant state of the art in accordance with Rule 64.1(b) in the same way as it would act in order to establish a more accurate publication date for a paper published document.
- Disclosures Made on Web Sites of Unknown Reliability
- 11.16 Examples of such web sites include those belonging to private individuals, private organizations (for example, clubs), commercial web sites (for example, advertising) etc. Where such an Internet disclosure is retrieved during the international search and it does not give any explicit indication of the publication date in the text of the disclosure, the Authority may consider using those technical means available to it to attempt to reveal the publication date.

11.17 Such technical means include:

- (a) information relating to the publication date embedded in the Internet disclosure itself (date information is sometimes hidden in the programming used to create the web site, but is not visible in the web page as it appears in the browser),
- (b) indexing dates given to the web page by search engines (these are usually later than the actual publication date of the disclosure since the search engines usually take some time to index a new web site) and
- (c) information available relating to the web site on commercial Internet archiving databases (for example, the "Internet Archive Wayback Machine").
- 11.18 Where the examiner obtains an electronic document which establishes the publication date for the Internet disclosure, he should make a print-out of this document, which must mention both the URL of the relevant Internet disclosure and the date of publication of that relevant Internet disclosure. The examiner must then cite this print-out in the international search report as an "L" document and cite the relevant Internet disclosure according to the relevance of its content ("X", "Y", "A") and according to the date as established ("X", "Y", "A", "P,X", "P,Y", "P,A", "E", etc.). Where the examiner is unable to establish the publication date of the relevant Internet disclosure and it is relevant to the inventive step and/or novelty of the claimed invention, he should cite it in the international search report with the category "L" for those claims which it would have affected if it were published in time and giving it the date it was printed out as the publication date (see paragraph 16.75(b).
- 11.19 Where this type of Internet disclosure does explicitly mention a publication date and this publication date:
- (i) is not contradicted by the information sources mentioned above (in this regard it should be noted that the indexing date given by a search engine is usually later than the

actual publication date and so where the examiner uncovers an indexing date for an Internet disclosure which is later than the publication date given in the Internet disclosure itself; this does not necessarily mean that the Internet disclosure was made available later than it claimed, it simply means that it was indexed by that search engine after it was made available); and

(ii) is accurate enough to establish if the document was published early enough to be considered relevant according to Rule 33.1(a) and Rule 64.1(b),

then the examiner should trust the date given and give this as the publication date in the search report and use this publication date in preliminary examination. The onus is on the applicant to prove otherwise.

11.20 In the absence of evidence to the contrary, the examiner should assume that the content of the Internet disclosure has not changed over time.

Differences Between Patent and Non-Patent Citations

Rule 64.3

11.21 As a general rule, no non-patent document is cited in the international search report if the date of publication or public availability of the document concerned is clearly the same as, or later than, the filing date of the international application. However, patent documents published on or after the filing date of the searched application are cited in the search report if the filing or priority date of such published application is earlier than the filing date of the searched application (see paragraph 11.07). Such published patent documents, although cited in the search report, are not considered as prior art for the purposes of Article 33(2) and (3), but are mentioned in the preliminary examination report.

Documents Reproducing an Earlier Oral Description

Rule 64.2

11.22 Where an oral description (for example, public lecture) or a prior use or sale (for example, display at a public exhibition) was publicly available before the relevant date of the international application but a document, which reproduces the oral description or gives an account of the prior use or sale, was published on or after the relevant date of the international application, that document may be cited in the international search report. The earlier lecture, display or other event is not treated as part of the prior art for purposes of the opinion on novelty and inventive step under Article 33(2) and (3), but the written opinion and international preliminary examination report calls attention to such non-written disclosure in the manner provided for in Rule 70.9.

Difficulty in Establishing Date of a Document

11.23 The international search may uncover a document where there is difficulty in establishing whether the date of publication or public availability of the document is or is not the same as, or later than, the filing date of the international application. The International Searching Authority should try to remove any doubt that may exist. Additional documents providing evidence in the case of doubt may be cited. Any indication in a document of the date of its publication should be accepted as correct by the examiner unless proof to the contrary has been offered, for example, by the International Searching Authority, showing earlier publication, or by the applicant, showing later publication. It may sometimes be possible to establish the precise date of publication of a document, for example by the date of receipt in a library to which the public has access or by relying on sources such as the "Internet Archive Wayback Machine" to establish dates of web sites. If the applicant presents sound reasons for doubting that the document forms part of the prior art in relation to his international application and any further investigation does not produce evidence sufficient to remove that doubt, the examiner should not pursue the matter further.

Relevant Date in Relation to Individual Claims or Parts of Claims

Rule 64.1(b)

- 11.24 It should be noted that the "relevant date," for the purpose of considering prior art, is defined in Rule 64.1(b) as meaning the international filing date or, where the international application contains a valid claim to priority, that date of priority (see also paragraphs 6.03 and 6.04). It should be remembered also that different claims, or different alternatives claimed in one claim, may have different relevant dates.
- 11.25 The questions of novelty and inventive step must be considered against each claim (or part of a claim where a claim specifies a number of alternatives) and the prior art in relation to one claim, or to one part of a claim, may include matter which cannot be cited against another claim, or part of a claim, because the latter has an earlier relevant date. Of course, if all the matter in the prior art was made available to the public before the date of the earliest priority document, the examiner need not (and should not) concern himself with the allocation of priority dates.
- 11.26 The validity of priority dates for a claim or a part of a claim is considered in detail in chapter 6.

Chapter 12 Novelty

Meaning of Novelty

- 12.01 For the purposes of the opinion given by an international preliminary examination, the invention, as defined by a claim, lacks novelty if every element or step is explicitly or inherently disclosed within the prior art defined in Rule 64.1 (see paragraphs 11.01 and 11.04), including any features implicit to a person skilled in the art (see paragraph 13.11 for a definition of the "person skilled in the art"). Inherency requires that the extrinsic evidence relied on by the examiner must make clear that the missing descriptive matter is necessarily present in the reference, and that it would be so recognized by persons skilled in the art. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. Well-known equivalents not disclosed within a prior art document are not considered when assessing novelty; this is a matter of obviousness (see Chapter 13 Inventive Step). Naturally the same considerations apply when producing a written opinion and in selecting documents for inclusion in the international search report (except that in this case the relevant date may be different, see paragraphs 11.02 and 11.05).
- 12.02 The prior art disclosure must enable a person skilled in the art to carry out the claimed invention. Ordinarily, enablement may be inferred by the examiner when considering patent documents (published applications and issued patents) within the prior art. When considering non-patent literature that on its face raises a question as to enablement, the examiner should determine that the prior art would have enabled a person skilled in the art to carry out the claimed invention. When determining whether a particular document is enabling and therefore defeats novelty, knowledge from outside the prior art document may be considered where appropriate. See the appendix to this chapter for additional guidance regarding what knowledge from outside the prior art document may be considered when making this determination. A chemical compound, the name or formula of which was mentioned in a document, is not considered as known unless the information in the document, together, where appropriate, with other knowledge generally available to a person skilled in the art, enable it to be prepared and separated or, for instance in the case of a product of nature, only to be separated. A prior art document that does not defeat novelty because it is not enabling for the claimed invention may nonetheless be relied upon in determining whether the claimed invention lacks inventive step. See Chapter 13.

Considerations in Determining Novelty

Methodology

- 12.03 For the assessment of novelty, the examiner should apply the following steps:
 - (i) evaluate the elements of the claimed invention;
- (ii) determine if a document under consideration forms part of the "prior art" (see paragraphs 11.01 to 11.05);
- (iii) assess whether each and every element or step of the claimed invention was explicitly or inherently disclosed in combination by the document, to a person skilled in the art, on the date of publication of the document.

Inherent or Implicit Disclosure

12.04 Lack of novelty may be apparent from what is explicitly stated in a published document, or it may be apparent from an inherent or implicit teaching of the document. For example, where the elastic properties of rubber are relied upon in a document that does not explicitly state that rubber is an "elastic material," a claim to an "elastic material" is anticipated because the rubber taught in the prior art inherently is an "elastic material". Alternatively, lack of novelty may be implicit in the sense that, in carrying out the teaching of

the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. Lack of novelty of this kind should be raised by the examiner only where there can be no reasonable doubt as to the practical effect of the prior teaching. Otherwise it should be considered in respect of inventive step (see Chapter 13).

Interpretation of Claims

12.05 In interpreting claims for the consideration of novelty, the examiner should have regard to the guidance given in paragraphs 5.20 to 5.41. In particular, the examiner should remember that statements in the claim reciting the purpose or intended use must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or in the case of process claims, a difference in the process steps) between the claimed invention and the prior art. Non-distinctive characteristics of a particular intended use should be disregarded (see paragraphs 5.21 to 5.23). For example, a claim to a substance X for use as a catalyst would not be considered to be novel over the same substance known as a dye, unless the use referred to implies a particular form of the substance (for example, the presence of certain additives) which distinguishes it from the known form of the substance. That is to say, characteristics not explicitly stated but implied by the particular use should be taken into account. For example, if a claim refers to a "mould for molten steel", this implies certain limitations for the mould. Therefore a plastic ice cube tray with a melting point much lower than that of steel would not come within the claim which would thereby be considered as being novel.

Combining Documents

12.06 It should be noted that in considering novelty (as distinct from inventive step), it is not permissible to combine separate items of prior art together (see paragraph 13.12). However, if a document (the "primary" document) refers explicitly to a second document (for example, as providing more detailed information on certain features), the teachings of the second document may be regarded as incorporated into the primary document to the extent indicated in the primary document. Equally, it is permissible to use a dictionary or similar document of reference in order to interpret how a special term used in the primary document would have been understood on the date of publication. It is also permissible to rely on additional documents as evidence to show that the disclosure of the primary document was sufficient (for example, for a chemical compound to be prepared and separated or, in the case of a product of nature, to be separated). See paragraph 12.02 and the appendix to this chapter. It is also permissible to rely on additional documents as evidence to show that a characteristic not disclosed in the primary document was inherent in the primary document on the date of publication of the primary document (for example, documents that teach rubber to be an "elastic material" for the example set forth in paragraph 12.04).

Alternatives

12.07 Where a claim contains alternatives, for example Markush claims (P1, P2, P3 ... Pn), any alternatives disclosed in the prior art are anticipated.

Generic vs. Specific Disclosures

- 12.08 Where a claim recites an invention in generic terms, for the determination of novelty, the disclosure of a specific example falling within the parameters of the generic claim anticipates the generic claim. For example, a disclosure of copper in a prior art document defeats the novelty of metal as a generic concept, but not the novelty of any metal other than copper, and a disclosure of rivets defeats the novelty of fastening means as a generic concept, but not the novelty of any specific fastening means other than rivets.
- 12.09 An item of prior art that discloses a genus does not always anticipate a claim to a species falling within the genus. In other words, if a claim under examination recites a specific example, and that specific example is not explicitly named but falls within a generic disclosure found in an item of prior art, the claim is not anticipated unless the specific example is identified with sufficient specificity in the item of prior art. If the item of prior art

identifies the claimed example with sufficient specificity, that example lacks novelty no matter how many other species are additionally described in the item of prior art.

Ranges

12.10 A specific example in the item of prior art which is within a claimed range anticipates the range claimed. Therefore, where, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated if one of them is described in the item of prior art. For example, a claim to titanium (Ti) alloy with 0.6 to 0.7% nickel (Ni) and 0.2 to 0.4% Molybdenum (Mo) would be anticipated by an item of prior art that describes a Ti alloy containing 0.65% Ni and 0.3% Mo. Where an item of prior art discloses a range which touches, overlaps or is within the claimed range, but does not disclose a specific example falling within the claimed range, a case by case determination must be made as to the novelty of the claim. In order to anticipate the claim, the claimed subject matter should be disclosed with sufficient specificity in the item of prior art. If the claim is directed to a narrow range, the item of prior art discloses a broad range, and the claimed narrow range is not merely one way of carrying out the teaching of the item of prior art (for example, there is evidence that the effect of the selection (for example, unexpected results) occurred in all probability only within the claimed narrow range), depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with sufficient specificity in the prior art in order to anticipate the claims (a selection invention). The unexpected results may also render the claims unobvious. See Chapter 13 – Inventive Step.

Appendix to Chapter 12

A12.02 The International Searching and Preliminary Examining Authorities have divergent practices with regard to what extrinsic knowledge may be considered when determining whether a particular item of prior art sufficiently discloses the claimed invention to defeat novelty. Some Authorities follow the first guideline below, while other Authorities follow the second guideline below. Authorities that do not follow these guidelines may nevertheless rely on the prior art document in determining whether the claimed invention lacks inventive step.

A12.02[1] The prior document must provide a sufficient disclosure on its effective date. By "effective date" is meant the publication date in the case of a previously published document. Authorities following this practice require the prior document, together with knowledge generally available on the effective date of the document, to provide a sufficient disclosure of every element or step of the claimed invention to a person skilled in the art.

A12.02[2].1 The prior document must provide a sufficient disclosure on the "relevant date" of the claim being searched or examined. See paragraph 11.03 for a definition of the relevant date for international search report purposes. See paragraphs 11.04 and 11.05 for a definition of the relevant date for written opinion and international preliminary examination purposes.

A12.02[2].2 Authorities following this practice consider knowledge that became available after the publication date of the prior document but before the relevant date of the claim being searched or examined to determine whether the prior document provided a sufficient disclosure of every element or step of the claimed invention to a person skilled in the art.

Chapter 13 Inventive step

Meaning of Inventive Step

- 13.01 A claimed invention is considered to involve an inventive step if, having regard to the prior art as defined in the Regulations (see paragraph 11.01), it is not, at the relevant date (see paragraphs 11.02 to 11.05) obvious to a person skilled in the art. Novelty and inventive step are different criteria. A claim lacks novelty if every element or step is explicitly or inherently disclosed within the prior art (see paragraph 12.01). The condition of inventive step/non-obviousness is fulfilled if the invention as a whole, compared to the prior art as a whole, would not have been obvious to a person skilled in the art. Multiple items of prior art may be combined in the determination of whether the requirement of inventive step/non-obviousness is met. Therefore, the examiner should take into consideration the claim's relation not only to individual documents or parts thereof taken separately but also to combinations of such documents or parts of documents, where such combinations are obvious to a person skilled in the art.
- 13.02 The "prior art" for the purposes of considering inventive step is as defined in Article 33(3) (see Chapter 11); it does not include later published applications or patents although, in the circumstances mentioned in paragraph 11.07 (see also paragraph 16.46), a later published application or patent may be cited in the international preliminary examination report.

Considerations in Determining Inventive Step

What Is "Obvious"?

- 13.03 The question to consider, in relation to any claim defining matter for which protection is sought, is whether, at the relevant date of that claim, it would have been obvious to a person skilled in the art to arrive at something falling within the terms of the claim having regard to the art known at that time. If so, the claim is considered to lack inventive step. The term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, that is, something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. The following are the basic considerations that apply in determining inventive step/non-obviousness:
 - (i) the claimed invention must be considered as a whole;
- (ii) the references must be considered as a whole and the skilled person must be motivated or prompted into combining the teaching of the documents so as to arrive at the subject matter as claimed including consideration of a reasonable expectation or likelihood of success; and
- (iii) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.

Light of Later Knowledge

13.04 In considering inventive step, as distinct from novelty (see paragraph 12.02 and the appendix to Chapter 12), it is fair to construe any published document in the light of subsequent knowledge and to have regard to all the knowledge generally available to the person skilled in the art at the relevant date of the claim.

Invention as a Whole; Combination of Known or Obvious Elements

13.05 In determining inventive step (non-obviousness), the invention claimed must normally be considered as a whole. In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious but whether the claimed invention as a whole would have been obvious. Thus, it is not

correct as a general rule, in the case of a combination claim, to argue that the separate features of the combination, taken by themselves, are known or obvious and that "therefore" the whole subject matter claimed is obvious. The only exception to this rule is where there is no functional relationship between the features of the combination. That is, where the claim is merely for a juxtaposition of features and not a true combination (see the example under paragraph 13.14(d)).

- 13.06 While the claim should, in each case, be directed to technical features (and not, for example, merely to an idea) in order to assess whether an inventive step is present, it is important for the examiner to bear in mind that there are various ways in which a person skilled in the art may arrive at an invention.
- 13.07 In identifying the contribution any particular invention makes to the art in order to determine whether there is an inventive step, account should be taken first of what the applicant himself acknowledges in his description and claims to be known; any such acknowledgment of known art should be regarded by the examiner as being correct unless the applicant states he has made a mistake. However, the further prior art contained in the international search report or any additional document considered to be relevant may put the claimed invention in an entirely different perspective from that apparent from the disclosure by itself and, indeed, this cited prior art may cause the applicant voluntarily to amend his claims to redefine his invention. The general knowledge of the person skilled in the art should also be taken into account for the determination of inventive step. Also, the prior art must be enabling for what is taught therein, even if it is not the entirety of the claimed invention. Therefore, whatever combination of items of prior art and admission or general knowledge is used, this combination must provide enablement with respect to the claimed invention.

Assessing the Contribution Against the Prior Art

- 13.08 The following considerations should be applied in the assessment of inventive step/non-obviousness:
 - (i) determination of the scope of the claimed invention:
 - (ii) determination of the scope of the relevant item(s) of prior art;
 - (iii) determination of a person skilled in the art in the relevant case;
- (iv) identification of the differences and similarities between the relevant item(s) of prior art and the claimed invention;
- (v) assessment of whether the claimed invention as a whole would have been obvious to a person skilled in the art having regard to the relevant item(s) of prior art and the general knowledge of a person skilled in the art.
- 13.09 The invention as a whole is obvious if any item(s) of prior art or general knowledge of the person of skill in the art would have motivated or prompted the person of skill in the art on the relevant date (see paragraphs 11.02 to 11.05) to reach the claimed invention by substituting, combining or modifying one or more of those items of prior art with a reasonable likelihood of success. One particular way to determine inventive step is to apply the problem-solution approach, described in the appendix to this chapter.
- 13.10 In order to reach a final conclusion as to whether any claim includes an inventive step, it is necessary to determine the difference between the subject matter of that claim as a whole and the whole of the known art (so far as dependent claims are concerned see also paragraph 13.19). In considering this matter, the examiner should not proceed solely from the point of view suggested by the form of claim (prior art plus characterizing portion; see paragraphs 5.04 to 5.08). The examiner should identify the closest prior art as the basis for the assessment of inventive step. This is considered to be that combination of features derivable from one single reference that provides the best basis for considering the question of obviousness. In determining the scope of the disclosure of the items of prior art, in

addition to the explicit disclosure, an implicit disclosure, that is, a teaching which a person skilled in the art could reasonably draw from the explicit disclosure, should also be taken into account. The critical time for the determination of such disclosure is the claim date of the application concerned. The general knowledge of the person skilled in the art on the relevant date of the claim should also be taken into account.

The "Person Skilled in the Art"

13.11 The person skilled in the art should be presumed to be a hypothetical person having ordinary skill in the art and being aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "prior art," in particular, the documents cited in the international search report, and to have had at his disposal the normal means and capacity for routine experimentation. If the problem on which the invention is based and which arises from the closest prior art prompts the person skilled in the art to seek its solution in another technical field, the person skilled in the art in that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability. There may be instances where it is more appropriate to think in terms of a group of persons, for example, a research or production team, than a single person. This may apply, for example, in certain advanced technologies such as computers or telephone systems and in highly specialized processes such as the commercial production of integrated circuits or of complex chemical substances.

Combining Teachings

- 13.12 In considering whether there is inventive step as distinct from novelty (see Chapter 12), it is permissible to combine the teachings of two or more prior art references, for example, different published patents, or several teachings contained in the same prior art reference, such as one particular book, but only where such combination would be obvious to the person skilled in the art. In determining whether it would be obvious to combine the teachings of two or more distinct documents, the examiner should have regard to the following:
- (i) whether the nature and content of the documents are such as to make it likely or unlikely that the person skilled in the art would combine them;
- (ii) whether the documents come from similar or neighboring technical fields and if not, whether the documents are reasonably pertinent to the particular problem with which the invention was concerned.
- The combination, substitution or modification of the teachings of one or more items 13.13 of prior art may only lead to a lack of inventive step/obviousness where a person skilled in the art would have been motivated by the prior art or his general knowledge, with a reasonable likelihood, to combine, substitute or modify one or more items of prior art. Conversely, where such combination could not have been expected from a person skilled in the art, the requirement of inventive step (non-obviousness) would be met, even if each single item would have been obvious if taken individually. The combining of two or more parts of the same document would be obvious if there is a reasonable basis for the person skilled in the art to associate these parts with one another. It would normally be obvious to combine with other prior art documents a well-known text book or standard dictionary; this is only a special case of the general proposition that it is obvious to combine the teaching of one or more documents with the common general knowledge in the art. It would, generally speaking, also be obvious to combine the teachings of two documents, one of which contains a clear and unmistakable reference to the other. It should be noted that the motivation to modify the prior art teachings need not be the same as the applicant's. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by the applicant. The prior art may suggest the claimed invention, but for a different purpose or to solve a different problem. In some instances the content of a single

item of prior art may lead to a finding of lack of inventive step. Examples of such instances are described in the appendix to this chapter.

Examples

- 13.14 The following examples provide guidance, as to circumstances where a claimed invention should be regarded as obvious or where it involves a positive determination of an inventive step (non-obviousness). It is to be stressed that these examples are only guides for the examiners and that the applicable principle in each case is "was it obvious to a person skilled in the art?" Examiners should avoid attempts to fit a particular case into one of these examples where the latter is not clearly applicable. Also the list is not exhaustive.
- (a) Claimed inventions involving the application of known measures in an obvious way and in respect of which an inventive step is therefore lacking:
- (i) The teaching of a prior document is incomplete as to the entire claimed invention and at least one of the possible ways of supplying the missing claim feature(s) would naturally or readily occur to the person skilled in the art thereby resulting in the claimed invention.

Example: The claimed invention relates to a building structure made from aluminum. A prior document discloses the same structure and says that it is of lightweight material but fails to mention the use of aluminum. Aluminum is a light-weight material that is well known in the art to be useful as a building material.

(ii) The claimed invention differs from the prior art merely in the use of well-known equivalents (mechanical, electrical or chemical) possessing the same purpose, wherein the equivalency is recognized in the prior art. Note that the applicant's recognition within the international application that an element is equivalent to another, which had previously been used for a different purpose, does not mean that the use of this element instead of the other is obvious.

Example: The claimed invention relates to a pump-motor combination which differs from a known pump-motor combination solely in that the motor is hydraulic instead of an electric motor.

(iii) The claimed invention consists merely in a new use of a well-known material employing the known properties of that material.

Example: A washing composition containing as a detergent a known compound having the known property of lowering the surface tension of water, this property being known to be an essential one for detergents.

(iv) The claimed invention consists in the substitution in a known device of a recently developed material whose properties make it plainly suitable for that use (analogous substitution).

Example: An electric cable comprises a polyethylene sheath bonded to a metallic shield by an adhesive. The claimed invention lies in the use of a particularly newly developed adhesive known to be suitable for polymer-metal bonding.

(v) The claimed invention consists merely in the use of a known technique in a closely analogous situation (analogous use).

Example: The claimed invention resides in the application of a pulse control technique to the electric motor driving the auxiliary mechanisms of an industrial truck, such as a fork-lift truck, the use of this technique to control the electric propulsion motor of the truck being already known.

(b) Claimed inventions involving the application of known measures in a non-obvious way and in respect of which an inventive step is therefore present:

(i) A known working method or means when used for a different purpose involves a new, surprising effect.

Example: It is known that high-frequency power can be used in inductive butt welding. It should therefore be obvious that high-frequency power could also be used in conductive butt welding with similar effect. An inventive step would exist in this case, however, if high-frequency power were used for the continuous conductive butt welding of a coiled strip but without removing scale (such scale removal being ordinarily necessary in order to avoid arcing between the welding contact and the strip). The unexpected result is that scale removal is found to be unnecessary because at high frequency the current is supplied in a predominantly capacitive manner via the scale which forms a dielectric.

(ii) A new use of a known device or material involves overcoming technical difficulties not resolvable by routine techniques providing that the means for overcoming the technical difficulties are defined in the claim.

Example: The claimed invention relates to a device for supporting and controlling the rise and fall of gas holders, enabling the previously employed external guiding framework to be dispensed with. A similar device was known for supporting floating docks or pontoons but practical difficulties not encountered in the known applications needed to be overcome in applying the device to a gas holder.

(c) Obvious combination of features not involving an inventive step:

The claimed invention consists merely in the juxtaposition or association of known devices or processes functioning in their normal way and not producing any non-obvious working interrelationship.

Example: Machine for producing sausages consists of a known mincing machine and a known filling machine disposed end to end.

(d) Not obvious and consequently a combination of features involving an inventive step:

The combined features mutually support each other in their effects to such an extent that a new technical result is achieved. It is irrelevant whether each individual feature is fully or partly known by itself.

Example: A mixture of medicines consists of a painkiller (analgesic) and a tranquilizer (sedative). It was found that through the addition of the tranquilizer, which intrinsically appeared to have no pain-killing effect, the analgesic effect of the pain-killer was intensified in a way which could not have been predicted from the known properties of the active substances.

- (e) Obvious selection or choice among a number of known possibilities not involving an inventive step:
- (i) The claimed invention consists merely in choosing from a number of equally likely alternatives.

Example: The claimed invention relates to a known chemical process in which it is known to supply heat electrically to the reaction mixture. There are a number of well-known alternative ways of so supplying the heat; the claimed invention resides merely in the choice of one alternative way of supplying the desired heat.

(ii) The claimed invention resides in the choice of particular dimensions, concentrations, temperature ranges or other parameters from a limited range of possibilities, and it is clear that these parameters or workable ranges were encompassed by the prior art and could be arrived at by routine trial and error or by the application of normal design procedures. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Example: The claimed invention relates to a process for carrying out a known reaction and is characterized by a specified rate of flow of an inert gas. The prescribed rates are merely those which would necessarily be arrived at by a person skilled in the art.

(iii) The claimed invention can be arrived at merely by a simple extrapolation in a straightforward way from the known art.

Example: The claimed invention is characterized by the use of a specified minimum content of a substance X in a preparation Y in order to improve its thermal stability, and this characterizing feature can be derived merely by extrapolation on a straight-line graph, obtainable from the known art, relating thermal stability to the content of substance X.

(iv) The claimed invention consists merely in selecting a small number of chemical compounds (that is, a subgenus or species) from a broad field of chemical compounds (genus).

Example: The prior art discloses a chemical compound characterized by a generic formula including a substituent group designated "R." This substituent "R" is defined so as to embrace entire ranges of broadly defined radical groups such as all alkyl or aryl groups either unsubstituted or substituted by halogen and/or hydroxy. Only a very small number of examples of specific embodiments within the broadly defined radical groups are disclosed in the prior art. The claimed invention consists in the selection of a particular radical or small group of radicals from among those well-known to be contained within the broadly defined radical groups disclosed in the prior art as the substituent "R". The prior art provides motivation to select any well-known member of the broadly defined radical groups and thus, provides motivation to one skilled in the art to make the modifications needed to arrive at the claimed compound(s). Moreover, the resulting compounds:

- are not described as having, nor shown to possess, any advantageous properties not possessed by the prior art examples; or
- are described as possessing advantageous properties, compared with the compounds specifically referred to in the prior art but these properties are ones which the person skilled in the art would expect such compounds to possess so that he is likely to be led to make this selection.
- (f) Non-obvious selection or choice and consequently inventive step among a number of known possibilities:
- (i) The claimed invention involves the special selection within a process, of particular operating conditions (for example, temperature and pressure) within a known range, such selection producing unexpected effects in the operation of the process or the properties of the resulting product.

Example: In a process where substance A and substance B are transformed at high temperature into substance C, it was known in the prior art that there is in general a constantly increased yield of substance C as the temperature increases in the range between 50 and 130°C. It is now found that in the temperature range from 63 to 65°C, which previously had not been explored, the yield of substance C was considerably higher than expected.

(ii) The claimed invention consists in selecting particular chemical compounds (subgenus or species) from a broad field of compounds (genus), wherein the specific compounds selected have unexpected advantages.

Example: In the example of a substituted chemical compound given at (iv) under (e), above, the claimed invention again resides in the selection of the substituent radical "R" from the total field of possibilities defined in the prior art. In this case, however, not only does the invention embrace the selection of specific compounds from the possible

generic field of compounds and result in compounds that are described and shown to possess advantageous properties, but there are no indications which would lead the person skilled in the art to this particular selection rather than any other in order to achieve the described advantageous properties.

(g) Overcoming a technical prejudice:

As a general rule, there is an inventive step if the prior art leads the person skilled in the art away from the procedure proposed by the claimed invention. This applies in particular when the person skilled in the art would not even consider carrying out experiments to determine whether these were alternatives to the known way of overcoming a real or imagined technical obstacle.

Example: Drinks containing carbon dioxide are, after being sterilized, bottled while hot in sterilized bottles. The general opinion is that immediately after withdrawal of the bottle from the filling device, the bottled drink must be automatically shielded from the outside air so as to prevent the bottled drink from spurting out. A process involving the same steps but in which no precautions are taken to shield the drink from the outside air (because none are in fact necessary) could therefore involve an inventive step.

Other considerations

Ex Post Facto Analysis

13.15 It should be remembered that a claimed invention which at first sight appears obvious might in fact involve an inventive step. Once a new idea has been formulated, it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps. The examiner should be wary of *ex post facto* analysis of this kind. The prior art must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention. The teaching or suggestion to make the claimed invention must be found in the prior art and/or the general knowledge of the person skilled in the art and not based on the applicant's disclosure. A factor to be considered in determining the motivation or prompting for combining the prior art teachings is whether there would have been a reasonable expectation or likelihood of success in combining the collective suggestions in the prior art. In all cases, the examiner should seek to make a practical "real-life" assessment. The examiner should take into account all that is known concerning the background of the claimed invention and give fair weight to relevant arguments or evidence submitted by the applicant.

Technical Value, Long-Felt Needs

- 13.16 In order to establish the positive assertion that the claimed invention involves an inventive step (non-obviousness), the following factors should also be taken into account as secondary considerations:
 - (i) whether the claimed invention fulfills a long-felt need;
 - (ii) whether the claimed invention overcomes a scientific prejudice;
- (iii) whether others have previously attempted, but failed to achieve what the claimed invention achieves;
 - (iv) whether the claimed invention involves an unexpected result; and
 - (v) whether the claimed invention has a particular commercial success.
- 13.17 If, for example, a claimed invention is shown to be of considerable technical value and, particularly, if it provides a technical advantage which is new and surprising and this can be convincingly related to one or more of the features included in the claim defining the invention, the examiner should be hesitant in raising a negative determination that such a claim lacks inventive step. The same applies where the claimed invention solves a technical

problem which workers in the art have been attempting to solve for a long time, or otherwise fulfills a long-felt need, or overcomes a scientific prejudice.

Commercial Success

13.18 Commercial success alone is not to be regarded as indicative of inventive step, but evidence of immediate commercial success when coupled with evidence of a long-felt want is of relevance provided the examiner is satisfied that the success derives from the technical features of the claimed invention and not from other influences (for example, selling techniques or advertising) and is commensurate in scope with the claimed invention.

Dependent Claims

Rule 6.4(b)

13.19 The examiner should bear in mind that, when considering whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable, a dependent claim is regarded as limited by all the features of the claim on which it depends. Therefore, if the statement concerning novelty of the independent claim is positive, it should normally be positive for the dependent claims. This principle applies to inventive step and industrial applicability as well, unless the dependent claim contains an additional feature which makes the invention industrially inapplicable.

Appendix to Chapter 13

Problem-Solution Approach

- A13.08.1 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 paragraph 13.08);
 - 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

- A13.08.2 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

- A13.08.3 In the second stage one establishes in an objective way the technical problem to be solved. To do this, one studies the claimed invention, the closest prior art, and the difference in terms of features (structural and functional) between the claimed invention and the closest prior art, and then formulates the technical problem.
- A13.08.4 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 claimed invention provides over the closest prior art.
- A13.08.5 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.

A13.08.6 The expression <u>"technical problem"</u> 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.

A13.08.7 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

A13.08.8 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."

A13.08.9 Note that the requirement of technical progress is not a requirement for the problem-solution approach. 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.

Examples in which a single document calls into question the inventive step

- A13.13 Under the practice of some Authorities, a document whose content alone calls into question the inventive step of at least one independent claim, and possibly that of one or more claims depending on it would be categorized as "X". The following are examples of situations in which this may occur:
- (i) where a technical feature known in a technical field is applied from its original field to another field and its application therein would have been obvious to a person skilled in the art:
- (ii) where a difference between the document's content and the claimed matter is so well known that documentary evidence is unnecessary;
- (iii) where the claimed subject matter relates to the use of a known product, and the use would have been obvious from the known properties of the product;
- (iv) where the claimed invention differs from the known art merely in the use of equivalents that are so well known that the citation of documentary evidence is unnecessary.

Chapter 14 Industrial Applicability

Meaning of Industrial Applicability

Articles 5, 33(4), 34(4)(a)(ii), 35(3)(a)

- 14.01 A claimed invention is considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. The term "industrially applicable" may be deemed by an International Authority to be synonymous with the term "utility". See the appendix to this chapter.
- 14.02 "Industry" is understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property. Industry therefore includes any physical activity of a technical character, that is, an activity which belongs to the useful or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article and could cover a process for dispersing fog, or a process for converting energy from one form to another.
- 14.03 Focusing on the general common characteristics of the industrial applicability and utility requirements, an invention that is inoperative, for example, an invention which is clearly non-operable in view of well-established laws of nature, does not comply with either the industrial applicability requirement or the utility requirement. This type of invention is considered either as having no application in industry or as not being useful for any purpose, because it doesn't work.

Methodology

- 14.04 For the assessment of industrial applicability, the following steps are applied:
 - (i) determine what the applicant has claimed; and
- (ii) determine whether a person skilled in the art would recognize the claimed invention to have industrial applicability.
- 14.05 In most cases, industrial applicability will be self-evident and no more explicit description on this point will be required.

Rules 43bis, 66.2(a)(ii), 70.8

14.06 If any product or process is alleged to operate in a manner clearly contrary to well-established physical laws and thus the invention cannot be carried out by a person skilled in the art, the claim does not have industrial applicability and the applicant should be so notified.

Appendix to Chapter 14

A14.01 Not all International Authorities have the same requirements for industrial applicability. An International Authority may rely upon either of the alternative guidelines below as appropriate.

Utility

A14.01[1] The term "industrially applicable" may be deemed by an International Authority to be synonymous with the term "utility." Accordingly, a claimed invention is considered industrially applicable if it has a utility that is: (a) specific, (b) substantial, and (c) credible.

Specific, or Particular, Utility

(a) It is necessary to distinguish between situations where an applicant has disclosed a specific use or application of the invention, and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating

unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of specific DNA target. A general statement that a compound could be used to diagnose a disease would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity of a compound and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant.

Substantial, or Practical "Real World" Utility

- (b) Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a compound for treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. It is necessary to distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining whether an applicant has identified a specific and substantial utility for the invention. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities:"
- (i) basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved:
- (ii) a method of assaying for or identifying a material that itself has no specific and/or substantial utility;
- (iii) a method of making a material that itself has no specific, substantial, and credible utility; and
- (iv) a claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Credible Utility

(c) An assertion is credible unless (i) the logic underlying the assertion is seriously flawed, or (ii) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility, as used in this context, refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. One situation where an assertion of utility would not be considered credible is where a person skilled in the art would consider the assertion to be "incredible in view of contemporary knowledge" and where nothing offered by the applicant would counter what contemporary knowledge might otherwise suggest. Claims directed to a compound for curing a disease or vaccinating against a disease for which there have been no previously successful cures or vaccines warrant careful review for compliance with the industrial applicability requirement. The credibility of an asserted utility of a compound for treating a human disorder may be more difficult to establish where current scientific understanding suggests that such a task would be impossible. Such a determination has always required a good understanding of the state of the art as of the time that the invention was made. The fact that there is no known cure for a disease, however, cannot serve as the basis for a

conclusion that such an invention lacks industrial applicability. Rather, it is necessary to determine whether the asserted utility for the invention is credible, based on the information disclosed in the application.

Industrial Applicability

- A14.01[2].1 Some International Authorities consider claimed subject matter to have industrial applicability only when all of the following requirements have been met; otherwise industrial applicability is lacking:
- (1) The international application must indicate the way in which the invention is capable of exploitation in industry (its intended function, special purpose or specific use).
- (2) The international application must disclose the invention in a manner sufficiently clear and complete (defining means and ways) for the invention to be carried out by a person skilled in the art. In the absence of such information it is permissible that the manner for carrying out the invention is disclosed in a source that was available to the public before the date of priority of the invention.
- (3) It must actually be possible while carrying out any claim (or claims) by a person skilled in the art to realize the indicated special purpose (specific use) of the invention.

Special Purpose

A14.01[2].2 It should be noted that as a rule the special purpose is readily apparent from the subject matter as defined in a claim (or claims) or from the nature of the invention. For example, when defining the subject matter of the invention as "computer" no question would arise of whether it is possible to use it in industry, that is, that requirement (1) would be considered to be complied with. On the other hand, if the subject matter of the invention refers to a novel chemical compound or a process for producing a novel compound, the invention would not be considered as complying with requirement (1) if the indication of its specific use is lacking in the international application.

Clear and Complete Disclosure

A14.01[2].3 The application is deemed to describe the invention in a manner complying with requirement (2) if the information contained in the international application, together with information available from a source that was available to the public before the priority date of the invention, is sufficient for the claimed subject matter to be carried out by a person skilled in the art. The information provided by the application is appreciated not only from the point of view of its use for carrying out the invention but also from the point of view of its use for finding the required information in the prior art. For example, suppose an independent claim defines a purported technical feature as follows: "heat expansion ratio for material from which a unit Q of a mechanism is made is in the range from A to B." Where the material having a heat expansion ratio in the range is known from the prior art, the application shall be deemed to disclose the invention in a manner complying with requirement (2) regardless of whether the material is identified in the application or not. Where such material is not known from the prior art, but the application contains information that is sufficient to manufacture the material, requirement (2) is deemed to be satisfied.

A14.01[2].4 On the other hand, requirement (2) in the example given above would not be deemed to have been complied with where a material having a heat expansion ratio in said range is neither known from the prior art nor can be manufactured because the international application as filed does not contain any information relating to its composition or its method of manufacture.

Possibility of Realizing the Special Purpose

A14.01[2].5 Verification of compliance with requirement (3) is, in fact, a verification of the technical correctness of the invention as defined in each claim. A positive result of such verification means that the implementation of the invention in accordance with the purported

technical features as set forth in the claim will result in an embodiment capable of being used for the indicated special purpose.

A14.01[2].6 As an example, when the subject matter of the claim is "perpetuum mobile" it would not be recognized as complying with requirement (3) even where the international application complies with requirement (2), since it operates contrary to the well-established physical laws. Requirement (3) is also deemed not to have been complied with in cases of technical errors which are not necessarily linked with basic laws of nature but nevertheless result in a failure of the claimed subject matter to be usable for the special purpose indicated by the applicant.

A14.01[2].7 As another example, when a motor is claimed, requirement (3) would be deemed to have been complied with if the functioning of the motor results in, say, mechanical movement. If at the same time it is found that certain characteristics, for example, the specified efficiency ratio of a motor, described in the international application cannot be achieved, this finding is of no relevance in the context of the industrial applicability requirement, but is to be treated under the sufficiency of description requirement.

Date at Which Requirements Must Be Met

A14.01[2].8 Verification of the compliance with requirements (1) to (3) is carried out as of the priority date of the invention. Accordingly, if no prior disclosure made before the priority date provided the information required to carry out the claimed invention and the earlier application on the basis of which priority of the application concerned was claimed did not contain such information, incorporation of the information into the application under review would not be sufficient to establish the invention as having industrial applicability as of the priority date and would be considered as adding new matter in contravention of Articles 19(2) and 34(2)(b).

PART IV THE INTERNATIONAL SEARCH

Chapter 15 The International Search

Objective of the International Search and Supplementary International Search

Article 15(2), and (4); Rules 33.1(a), and 34

- 15.01 The objective of the international search is to discover relevant prior art, which consists of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) (see Chapter 11) and which is capable of being of assistance in determining that the claimed invention is or is not new (see Chapter 12) and that it does or does not involve an inventive step (that is, that it is or is not obvious; see Chapter 13), provided that the making available to the public occurred prior to the international filing date. The International Searching Authority endeavors to discover as much of the relevant prior art as its facilities permit, and in any case consults the minimum documentation specified in Rule 34.
- 15.02 In order to establish the international search report, International Searching Authorities are also encouraged to cite prior art documents which might be of assistance in determining whether other requirements such as sufficiency, support and industrial applicability are fulfilled.
- 15.03 The search must recognize that certain designated Offices have different definitions of what is the effective date of the prior art. Accordingly, when performing the search, examiners should be mindful to pick out and select for citation, where appropriate, prior art which may be relevant in Offices other than the one in which they are situated. However, the examiner need not expand the search beyond the standard search parameters to discover such art. Where the search has been performed and such potentially relevant prior art has been identified, examiners are encouraged to, for example, cite all relevant art published prior to the international filing date even if that art and the international application under consideration have common applicants and/or inventors. Examiners should follow Article 11(3) in conducting the search, even if an Article 64(4) reservation exists.
- 15.04 A further objective of the international search is to avoid, or at least minimize, additional searching at the national stage.

Non-Written Disclosures

Rule 33.1(b)

15.05 A non-written disclosure such as an oral disclosure, use, exhibition or other means of disclosure is not relevant prior art for the purposes of the international search unless it is substantiated by a written disclosure made available to the public prior to the international filing date and it is the written disclosure which constitutes the prior art. However, if the date on which the written disclosure was made available to the public was on or after the filing date of the international application under consideration, the search report should separately mention that fact and the date on which the written disclosure was available, even though such a written disclosure does not meet the definition of relevant prior art in the international phase, so long as the non-written disclosure was made available to the public on a date prior to the international filing date (see paragraph 11.22) since such a non-written disclosure may be considered to be prior art under national law in the national phase.

Geographical Location, Language, Age and Manner of Disclosure

15.06 It is to be noted that there is no restriction whatever with respect to the geographical place where, or the language or manner in which, the relevant information was made available to the public; also no age limit is stipulated with respect to documents containing this information.

15.07 Documents issued electronically are considered published provided they are retrievable (see paragraphs 11.12 to 11.20).

The Examiner

Article 18; Rule 43

15.08 The international search is carried out and the international search report prepared by an International Searching Authority. The international search itself is normally performed by one examiner but is not limited to one. In appropriate cases, where the invention is of a nature requiring searching in widely dispersed specialized fields, an international search report containing the work of two or more examiners may be necessary.

Rule 43bis.1(a)

The examiner is also required to provide a written opinion on novelty, inventive step and industrial application applicability of the claimed invention at the same time as he establishes the international search report. The international search report and written opinion together serve to inform the International Preliminary Examining Authorities of the documents and arguments necessary to complete the relevant assessments themselves if a demand for international preliminary examination is demandedmade, as well as to informing the designated Offices for the purposes of their consideration of the application in the national phase (the written opinion being transmitted to them in the form of an international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty) if no international preliminary examination report is established under Chapter II of the Treaty). Consequently it is essential that the examiner is familiar with the requirements of examination.

Basis of the Search

Article 19; Rules 5.2, 13ter, 91.1; Section 208, Al Part 8, Al Annex C 15.10 There is no right to amend the application until after the international search has been established, consequently the international search must be carried out on the basis of the search copy of the application as transmitted to the International Searching Authority by the receiving Office, except that obvious errors mistakes may be corrected (see Chapter 8).

REFERENCE (R. 20.6)". These are pages containing missing parts which have been incorporated by reference from the priority document under Rules 4.18 and 20.6 by the receiving Office. Such pages should be considered as originally filed and should be so indicated on the forms. In case the examiner notices that the incorporated missing parts were not completely contained in the priority document, then it may be noted in the written opinion of the International Searching Authority (in the "Additional Comments" part of Box I) on the separate sheet that there are doubts as to whether the missing parts were actually completely contained in the priority document. In such a case the search report may further include additional documents ("L") which would be relevant if a re-dating of the application would be made. The application may also contain sheets stamped "Not to be considered (R. 20.5(e) or 20.7)". This means that these sheets were not allowed by the receiving Office under the above discussed provisions (for formal or substantive reasons) and the applicant has withdrawn those parts in order to avoid re-dating of the application. Such sheets thus do not belong to the application documents and should be ignored for search and examination.

Rule 13ter.1: Section 513

15.10_15.12 If the application contains disclosure of one or more nucleotide and/or amino acid sequences but does not contain a sequence listing complying with the relevant standard (see paragraph 4.15) or contains the sequence listing only in paper (or .pdfimage file) form, the International Searching Authority may invite the applicant (with Form PCT/ISA/225) to furnish, within a fixed time limit, a sequence listing in written paper (or .pdfimage file) form and/or in computer readableelectronic form complying with the standard for purposes of completion of the international search. The furnishing of a sequence listing in response to an invitation by the International Searching Authority may be subject to the payment of a fee set

by the International Searching Authority, which may not exceed 25% of the international filing fee (not taking into account any fee for each sheet of the international application in excess of 30 sheets). The International Searching Authority should not, however, require payment of any late furnishing fee if the absence of the sequence listing in a compliant form at the International Searching Authority was due to the receiving Office failing to forward an electronic sequence listing it had received for the purposes of Rule 13ter to the International Searching Authority, as required by Rule 23.1(c). If the applicant complies with the invitation, the International Searching Authority proceeds with the completion of the international search, the international search report or declaration of non-establishment of international search report, and the written opinion on the basis of the written paper (or page file) and/or computer readable electronic forms of the sequence listing provided. However, any sequence listing not contained in the international application as filed will not, subject to Article 34, form part of the international application, but will be used as a search tool. The Authority marks in the upper right hand corner of the first sheet of any such listing provided in paper form "SUBSEQUENTLY FURNISHED SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION " or their equivalent in the language of publication of the international application. If the applicant does not comply with the invitation within the time limit or if the response to the invitation does not comply with the standard, the International Searching Authority is not required to carry out the international search to the extent that such non-compliance has the result that a meaningful search cannot be carried eutrequired to search the international application only to the extent that a meaningful search can be carried out without the sequence listing.

Rules 5.2(b), 13ter.1(eff); Section 513; Al Annex C 15.11_15.13 Where the sequence listing part of the description contains free text as defined in the standard provided for in Annex C of the Administrative Instructions, but that free text does not also appear in the main part of the description in the language thereof, the International Searching Authority invites the applicant (with Form PCT/ISA/233) to correct the application by adding the free text to the main part of the description. If the applicant complies with the invitation, the International Searching Authority marks the replacement sheet with the words "SUBSTITUTE SHEET (RULE 13ter.1(ef))" or their equivalent in the language of publication of the international application and the date of receipt, and transmits the substitute sheets containing that free text to the receiving Office and the International Bureau for inclusion of the sheets concerned in the home copy and the record copy, respectively; it keeps a copy of those sheets for inclusion in the search copy. If the applicant does not comply with the invitation, the International Searching Authority nevertheless continues to perform the international search.

Rules 12.3, 23.1(b)

15.14 Where the language in which the international application is filed is not accepted by the International Searching Authority that is to carry out the international search, the applicant should have supplied to the receiving Office a translation of the international application into a suitable language, however no such translation is required of the request Form or any sequence listing included as part of the description. The receiving Office sends this translation as part of the search copy and the international search will be carried out on the basis of this translation.

Rules 4.12, 12bis

The applicant may request the International Searching Authority to take into account the results of an earlier search carried out by that Office or by another Office. In this case, either a copy of the earlier search report (or other document listing cited prior art) will be sent by the receiving Office with the search copy, or else the International Searching Authority will be requested to retrieve a copy for itself where either it prepared the earlier search report itself, or else has access to it in a form and manner acceptable to it, for example from a digital library.

- 15.16 The Authority may additionally invite the applicant (optionally using Form PCT/ISA/238) to furnish the following items within a time limit reasonable under the circumstances, where they have not been transmitted by the receiving Office and are not already available to it from its own records or from a digital library which it is prepared to use for the purpose (and, if necessary, where the applicant has informed the Authority that the document is so available):
 - (i) a copy of the earlier application concerned;
- (ii) where the earlier application is in a language which is not accepted by the International Searching Authority, a translation of the earlier application into a language which is accepted by that Authority;
- (iii) where the results of the earlier search are in a language which is not accepted by the International Searching Authority, a translation of those results into a language which is accepted by that Authority;
 - (iv) a copy of any document cited in the results of the earlier search.

However, no copy or translation of the earlier application may be required if the applicant indicates in the request that the earlier application is "the same, or substantially the same" as the international application. By this, it is meant that the inventions described and claimed are the same and any changes, beyond accurate translation where relevant, relate solely to formatting and correction of minor errors, inclusion or removal of matter not specific to the invention, but which is required in some States (such as details of public funding used in the development of the invention).

Rules 16.3 and 41.1

15.17 Where the earlier search which the applicant requests to be taken into account was carried out by the same Office which is acting as an International Searching Authority, that Authority must, to the extent possible, take the results into account in establishing the international search report. Where the earlier search was conducted by another Office, the Authority may take the results into account. "Taking the results into account" in this context means finding a real benefit in those results to the extent that the earlier search may be considered to stand in place of at least a part of the international search. In any case, the examiner should consider the fields of search and cited documents in order to determine their relevance and whether they offer assistance in determining appropriate databases, classifications or terms of art in order to improve the quality of the international search.

Scope of the International Search

Articles 18(2), 20(1)(a), 21(3), 33(6)

- 45.1215.18 The international search is essentially a thorough, high quality, search of the most relevant resources, and the report serves to provide information on the relevant prior art to the applicant, to the public if the international application is published and to the designated Offices and the International Preliminary Examining Authorities.
- 45.13_15.19 In some instances there are no facilities for systematic searching by the designated Offices. The examiner should, therefore, assume that the designated Offices are dependent on the work of the International Searching Authorities for their knowledge of the state of the art on which their assessments of the patentability of the claimed invention will be based.
- 45.1415.20 Nevertheless, it must be realized that, even though completeness should be the ultimate goal of the international search, this goal may not be necessarily obtained, because of such factors as text search limitations and the inevitable imperfections of any classification system and its implementation, and may not be economically justified if the cost is to be kept within reasonable bounds. The examiner therefore considers the most relevant search resources for the technology, including databases listed in the Search Guidance

Intellectual Property Digital Library (IPDL) (available through the WIPO web site at www.wipo.int), and organizes the search effort and utilizes the search time in such a manner as to reduce to a minimum the possibility of failing to discover existing highly relevant prior art, such as complete anticipations for any claims. For less relevant prior art a lower retrieval ratio is acceptable.

Orientation and Subject of the International Search

Analysis of the Claims

| 15.15_15.21 When taking up an international application to be searched, the examiner first considers the application in order to determine the subject of the claimed invention, taking account of the guidance given below and in Chapter 5. For this purpose, the examiner makes a critical analysis of the claims in the light of the description and drawings.

Article 15(3); Rule 33.3(a) 15.1615.22 The international search is directed to the invention defined by the claims, as interpreted with due regard to the description and drawings (if any) and with particular emphasis on the inventive concept towards which the claims are directed. See Chapter 5 for the relationship between the disclosure and the claims.

Rule 43.6bis, Rule 91.1

15.17

Since the applicant is not permitted to amend the claims before receiving the international search report, except to rectify obvious errors-mistakes or to correct formal matters which are contrary to the PCT and are called to the applicant's attention by the receiving Office, the international search is directed to the claims as filed. See paragraph 15.25. This is subject to the exception where the rectification of an obvious mistake in the claims is authorized by the International Searching Authority according to Rules 91.1(b)(ii), (c) and (d) before it has begun to draw up the international search report, in which case the rectified claims are taken into account in the search and the international search report shall so indicate (Rule 43.6bis) (see paragraphs 8.18 and 8.19).

Inventions for Which No Fees Have Been Paid

Article 17(3)(a)

15.1815.24 When the claims of the international application do not relate to one invention only, nor to a group of inventions so linked as to form a single general inventive concept, the applicant may be invited (with Form PCT/ISA/206, see paragraphs 10.60 to 10.65) to pay additional search fees. If the applicant does not pay any additional search fees in response to the invitation, the international search will, except in the circumstances referred to in paragraphs 10.64 and 10.65, be restricted to those parts that relate to the invention, or so linked group of inventions, first mentioned in the claims. If additional fees have been paid within the prescribed time limit, those parts that relate to the inventions covered thereby must also be searched (see Chapter 10).

Full Coverage

Rule 33.3(b)

45.1915.25 In principle, and insofar as possible and reasonable, the international search should cover the entire subject matter to which the claims are directed or to which they might reasonably be expected to be directed after they have been amended. For example, where an international application relating to an electric circuit contains one or more claims only directed to the function and manner of operation, and the description and drawings include an example with a detailed non-trivial transistor circuit, the search must necessarily include this circuit. Nevertheless, reasons of economy may make certain restrictions of the international search necessary, for example, when there is a broad claim and many examples and it is not possible to foresee which will be the subject of amended claims.

Speculative Claims

45.2015.26 No special search effort need be made for searching unduly wide or speculative claims, beyond the extent to which they are supported by the description. For example, if in an international application relating to and describing in detail an automatic telephone exchange, the claims are directed to an automatic communication switching center, the international search should not be extended to automatic telegraph exchanges, data switching centers, etc., merely because of the broad wording of the claim, except if it is probable that such an extended search could produce a document on the basis of which a reasonable objection as regards lack of novelty or inventive step could be established. Likewise, if a claim is directed to a process for manufacturing an "impedance element" but the description and drawings, relate only to the manufacture of a resistor element, and give no indication as to how other types of impedance elements could be manufactured by the process of the claimed invention, extension of the search to embrace, say, manufacture of capacitors, would not normally be justified. However, if a meaningful search based on a claim that is not supported by the description can be carried out without much increase in effort, the search should be extended to cover the claimed subject matter that is not supported by the description if the scope of the claim is not unduly wide.

Dependent Claims

- 45.24_15.27 The international search carried out for the independent claim(s) must also take into consideration the subject matter of all dependent claims. Dependent claims are interpreted as being restricted by all features of the claim(s) upon which they depend. Therefore, where the subject matter of the independent claim is novel, that of the dependent claims is also considered novel for the purpose of international search. When the novelty and inventive step of the independent claim are apparent as a result of the international search, there is no need to make a further search in respect of the subject matter of the dependent claims as such.
- 45.2215.28 However, where the novelty or inventive step of the main claim is questioned, it may be necessary for assessing inventive step of a dependent claim to establish whether the features of the dependent claim as such are novel by expanding the field of search. No special search should be made for features that are so well known that documentary evidence seems to be unnecessary; however, if a handbook or other document showing that a feature is generally known can be found rapidly, it should be cited. When the dependent claim adds a further feature (rather than providing more detail of an element figuring already in the main claim), the dependent claim in effect constitutes a combination claim and should be dealt with accordingly (see paragraph 15.31).

Search of Particular Claim Types and Features

- 15.23 The words of a claim must be read as they would be understood by a person skilled in the art in accordance with the meaning and scope which they normally have in the relevant art. See paragraphs 15.20 to 15.28 for guidelines regarding interpretation of particular claim types and features.
- 45.2415.30 In two-part claims as defined by Rule 6.3(b) (known as "Jepson claims" under the practice of some Authorities), the claimed invention includes the limitations of the preamble in combination with the limitations in the characterizing portion of the claim. In these cases, the preamble is regarded as a limitation on the scope of the claim (see paragraph 5.22). In certain circumstances, it may be desirable to extend the subject matter of the international search to include the "technological background" of the claimed invention. This would include:
- (i) the preamble portion of the claim, that is, the part preceding the expression "characterized by" or "the improvement comprising";
- (ii) the state of the prior art as explained in the introduction of the description of the international application but not identified by specific citations; and

(iii) the general technological background of the invention (often called "general state of the art").

Combination of Elements

15.2515.31 For claims characterized by a combination of elements (for example, A, B and C), the international search should be directed towards the combination; however, when searching classification units (see Chapter 7) for this purpose, sub-combinations, including the elements individually (for example, AB, AC, BC and also A, B and C separately), should be searched in those units at the same time. A search in additional classification units either for sub-combinations or for individual elements of the combination should only be performed if this is still necessary for establishing the novelty of the element in order to assess the inventive step of the combination.

Different Categories of Claim

45.2615.32 When the international application contains claims of different categories that comply with the unity requirement (see Chapter 10), all these must be included in the international search. When the international application contains only claims of one category, it may be desirable to include other categories in the search. A reference describing a process of making a product but only claiming the product itself might only be classified in a subclass directed to the product and not be cross-referenced in a subclass directed to the process. Accordingly, when searching for a particular process of making a product it may be necessary to search for the product in order to discover the best prior art disclosing the process of making the product. As such, for example, except when the international application contains indications to the contrary, one may generally assume that in a claim directed to a chemical process, the starting products form part of the state of the art and need not be searched; the intermediate products will only be searched when they form the subject of one or more claims; but it is highly recommended that the final products always be searched, except when they are evidently known, since the most relevant prior art may only be classified in terms of the final products.

Cases Where No Meaningful Search Is Possible

Article 17(2)(a); Rules 39, 43bis.1, 66.2(a)(v)

45.27_15.33 _ The examiner, in general, excludes from the international search subject matter for which no searches are to be carried out, or for which no meaningful search can be made; this may result, for example, from the fact that certain subject matter may be excluded from the search under Rule 39, or from exceptional situations where no search at all is possible for a particular claim(s) (see paragraph 15.12 and Chapter 9). The examiner indicates in either Box No. II of Form PCT/ISA/210 (International Search Report) or Form PCT/ISA/203 (Declaration of Non-Establishment of International Search Report), as appropriate, the reasons for which no international search is established in respect of the relevant claims. In Box No. III of Form PCT/ISA/237 (Written Opinion of the International Searching Authority; see paragraphs 17.09, 17.33 and 17.34), it will then usually be sufficient to indicate that no international search report has been established for the relevant claims as the reason for not establishing an opinion on novelty, inventive step and industrial applicability and refer to the international search report or declaration for further details.

Obvious Errors Mistakes and Matter Contrary to Public Order

Rules 9.1, 9.2, 91.1, 33.3(b); Sections 501, 511(a)(v)

- | 15.2815.34 | If the examiner notices any obvious error mistake in the international application, the International Searching Authority may invite (optionally using Form PCT/ISA/216, see paragraph 8.13) the applicant to request the rectification of the error.
- | 15.2915.35 | Similarly, if the International Searching Authority notes matter contrary to public order ("ordre public") or morality or disparaging statements which ought to be omitted from the international application as published, it suggests to the applicant, with Form PCT/ISA/218, that the applicant voluntarily correct the international application and

notifies the receiving Office and the International Bureau accordingly. Note that any such correction must not introduce new matter (see Chapter 8). If the applicant does not make the requested corrections within the indicated time limit, the examiner proceeds with international search and examination covering subject matter to which the claims might reasonably be expected to be directed after amendment. However, it should be recognized that if the applicant does not make the requested corrections, the International Bureau may omit the noted matter from the publication of the international application, in accordance with Article 21(6).

45.3015.36 Any decision on a rectification under Rule 91.1 (Form PCT/ISA/217) or any correction aimed at complying with Rule 9.1 must be transmitted to the International Bureau; corrections aimed at complying with Rule 9.1 must also be transmitted to the receiving Office.

Search Strategy

Preliminary Steps

15.31_5.37 Documents cited in the international application should be examined if they are cited as the starting point of the invention, or as showing the state of the art, or as alternative solutions to the problem concerned, or when they are necessary for a correct understanding of the application; however, when such citations clearly relate only to details not directly relevant to the claimed invention, they may be disregarded. If the international application cites a document that is not published or otherwise not accessible to the International Searching Authority and the document appears essential to a correct understanding of the invention to the extent that a meaningful international search would not be possible without knowledge of the content of that document, the International Searching Authority may postpone the search and request the applicant to provide first a copy of the document, if possible to do so within the time limits for the preparation of the international search report under the PCT. If no copy of the document is received, the International Searching Authority should first attempt to carry out the international search and then, if necessary, indicate that no meaningful search could be carried out in total or that the search needed to be restricted.

Abstract and Title

Rules 37, 38

15.3215.38 The examiner then considers the abstract (together with the title of the invention and the figure of the drawings to be published with the abstract) in relation to the requirements of the Regulations under the PCT (see paragraph 16.37). Since the abstract should relate to the international application as filed, the examiner should consider it and determine its definitive contents no later than the completion of the international search report. Under certain circumstances (see paragraph 15.40), the examiner will have to establish the abstract and/or title, and/or select the figure to accompany the abstract for publication purposes. Such abstract is established in the language in which the international application is to be published or, if a translation into another language was transmitted under Rule 23.1(b) and the International Searching Authority so wishes, in the language of that translation.

Classification

15.3315.39 The examiner, after having considered the abstract, if any, then classifies the international application according to at least the International Patent Classification (IPC) (see Chapter 7).

Publication Prior to Search

Rules 8.2, 37.2, 38.2(a)

45.3415.40 If publication of the international application is due before the international search has been established, the examiner must, upon request by the International Bureau, establish the classification of the application before the search is carried out; the examiner, at the same time, examines the abstract (together with the title and selected figure) for the

purpose of publication. This examination of the abstract does not go beyond ensuring that it relates to the application concerned and that no conflict exists with the title of the invention or with the classification of the application. If at that time no abstract, title or figure selection has been provided by the applicant, the examiner does so. No abstract or title need be established where the International Searching Authority received a notification from the receiving Office to the effect that the applicant has been invited to furnish an abstract and/or title. Subject to the above, if the international search report is published later than the date of publication of the international application, the abstract published with the application will be as filed and the definitive abstract will be published together with the international search report.

Search Statement

Article 17(2)(a)

45.35_15.41 Having determined the subject of the invention, as outlined in paragraphs 15.21 to 15.23, it may be desirable for the examiner to prepare first a written search statement, defining the subject of his search as precisely as possible. In many instances, one or more of the claims may themselves serve this purpose, but they may have to be generalized in order to cover all aspects and embodiments of the invention. At this time, the considerations relating to the exclusion from international search (see Chapter 9) and to lack of unity of invention (see Chapter 10) should be borne in mind. The examiner may also have to restrict the international search in exceptional situations because no search at all is possible (see paragraphs 9.19, 9.26 to 9.30 and 9.40); but the examiner should not do this if it can be avoided (see paragraphs 9.17 and 9.19 to 9.25). Any restrictions of the international search on these grounds should be indicated in the international search report. If no search is made, a declaration should be issued under Article 17(2)(a).

<u>15.36</u> The claims should be construed and searched having particular regard to the various types and forms of claims used, such as two-part claims and product-by-process claims (see paragraphs 15.21 to 15.33).

Field of Search

Rule 34

15.3715.43 The International Searching Authority carrying out the international search endeavors to discover as much of the relevant prior art as its facilities permit, and, in any case, consults the appropriate minimum documentation specified in Rule 34, and considers relevant databases or other search resources such as those listed in the Search Guidance Intellectual Property Digital Library (IPDL), which appears on the World Intellectual Property OrganizationWIPO web site (www.wipo.int).

Rule 43.6(b)

45.3815.44 Thus, the International Searching Authority in searching an international application, in principle, consults all documents within the field of search that exists in the search files or databases, irrespective of their language or age, or of the type of document. Nevertheless, the examiner should, for reasons of economy, exercise appropriate judgment, based on his knowledge of the technology in question and of the documentation involved, to omit segments of the search file or databases in which the likelihood of finding any documents relevant to the international search is very small, for example, documents falling within a period preceding the time when the area of technology in question began to develop. Similarly the examiner need only consult one member of a patent family unless there is good reason to suppose that, in a particular case, there are relevant substantial differences in the content of different members of the same family or because only another member of a patent family was published before the international filing date and must therefore be cited in the first place.

Rule 33.2(a). and (b)

45.3915.45 The international search is carried out on the basis of the search files or databases which may contain material pertinent to the claimed invention. It covers all

directly relevant technical fields within the PCT minimum documentation. The search may then have to be extended to include other listed resources or databases, such as those listed in the Search Guidance IPDL, or to analogous fields, but the need for this must be judged by the examiner in each individual case, taking into account the outcome of the search in the initial fields. See paragraph 15.61.

- 45.40_15.46 The question of which of the listed relevant search resources, including the databases listed in the Search Guidance IPDL, are to be consulted in a given area of technology must be judged by the examiner in each individual case. Classification places to be included in the international search should be selected in all directly relevant fields and, if necessary, in analogous fields. The examiner should consider all relevant search resources for the technology field and determine those most appropriate for the international application. Search resources listed in the Search Guidance IPDL relevant to the technical areas may provide a useful guide for relevance to the application at hand. This includes, for example, specialized search systems, abstracting journals, and on-line databases. Where searches are made by using the IPC, the selection of classification places in analogous fields should be limited to:
- (i) higher subdivisions allowing searching by abstraction (generalization) inasmuch as this is justified from a technical viewpoint, and
- (ii) parallel subdivisions, bearing in mind the fact that the fields in question will become increasingly unrelated.
- 45.41_15.47 Often various search strategies are possible that are relevant to the subject matter of the application. The examiner should exercise judgment based on experience and knowledge of the search resources, to select the search strategies most appropriate to the case in hand, and establish the order in which various strategies (that is, classification places, databases, and other resources) are to be consulted accordingly. This process should give precedence to the main technical field of the international application, and to the search resources and strategies in which the probability of finding relevant documents is highest.

Analogous Fields

15.4215.48 The field of search should, where appropriate, include analogous fields to the extent they are consistent with the description and drawings.

Rule 33.2(c)

- 45.4315.49 The question of which arts are, in any given case, to be regarded as analogous is considered in the light of what appears to be the necessary function or use of the claimed invention and not only the specific functions expressly indicated in the international application.
- <u>15.4415.50</u> In determining analogous fields into which the search should be extended, it is useful to give consideration to:
- (i) fields in which the same or similar structure would be expected by a person skilled in the art to be employed in different work or use;
 - (ii) fields to which a generic concept of claimed features pertains;
- (iii) art within the field of the inventor's endeavor and reasonably pertinent to the particular problem with which the inventor was involved;
- (iv) fields relevant to the function or utility inherent in the subject matter covered by the claims, that is, the field to which the application is most likely to be applied would be searched in addition to the general field of the subject matter.
- 15.4515.51 The decision to extend the international search to fields not mentioned in the international application must be left to the judgment of the examiner, who should not try to imagine all the kinds of applications of the claimed invention that might have been envisioned

by the inventor. The overriding principle in determining the extension of the search in analogous fields should be whether it is possible that a reasonable objection that there is a lack of inventive step could be established on the basis of what is likely to be found by the search in these fields.

Conducting the Search

- 15.4615.52 The examiner carries out the international search, directing attention to any prior art likely to have bearing on novelty or inventive step. In addition, the examiner is encouraged to cite any prior art likely to be of assistance in determining sufficiency of description through the whole of the field claimed, per paragraphs 5.52 and 5.53 and the requirement that the claimed invention be fully supported by the description, per paragraphs 5.54 to 5.58. The examiner should also note any documents that may be of importance for other reasons, such as documents putting doubt upon the validity of any priority claimed, contributing to a better or more correct understanding of the claimed invention, or illustrating the technological background, but the examiner should not spend time in searching for these documents, nor in the consideration of such matters unless there is a special reason for doing so in a particular case. Documents which do not qualify as prior art because they post-date the claimed invention may nevertheless be cited to show a universal fact, such as characteristics or properties of a material, or a specific scientific fact, or to show the level of ordinary skill in the art.
- 45.4715.53 The examiner should concentrate the search efforts on the search resources and strategies in which the probability of finding highly relevant documents is greatest. Where the examiner intends to cite any prior art likely to be of assistance in determining sufficiency of description, then while conducting a search in a relevant area, the examiner should identify all documents, regardless of publication dates, which are highly relevant to the determination of novelty, inventive step, adequacy of support, and industrial applicability of the claimed invention. The examiner should always take account of the search results already obtained in considering whether to extend the search (that is, consult additional databases, broaden a search query, or include additional classification places).
- 45.4815.54 The examiner typically conducts a search of the patent literature first. In certain art areas, such as those identified in the Search Guidance IPDL (see paragraph 5.43), a search of the non-patent literature may be necessary. However, regardless of the art being searched, if little or no relevant patent prior art is located, the examiner should consider broadening the resources searched to include databases containing non-patent literature.
- <u>45.4915.55</u> Note that no special search should be made for features that are instantly and unquestionably demonstrable as being well known such that documentary evidence seems unnecessary. Preferably, however, a handbook or other document showing that a feature is generally known should be cited if practicable.

Security of Searching Using the Internet

45.50_15.56 When conducting a search on an international application, it may be necessary to make use of the Internet as a search tool. According to Rule 42.1, the international application must be searched within three months of receipt of the search copy by the International Searching Authority (or nine months after the priority date, if this expires later), and the receiving Office must usually forward the search copy to the International Searching Authority within one month of the international filing date (Rule 23.1(a)). This means that where the full priority year is claimed, the search will usually have to be performed at the very latest, within 16 months of the priority and consequently before international publication according to Article 21(2)(a). Where the international application has not yet been published at the time of the search, there exists the danger that search terms used in the search on non-secure Internet search engines or in databases available on the Internet may be observed by third parties. This may reveal details of the application before it is published, which is clearly undesirable. It should be stressed that it is common practice for Internet

sites to keep records of queries, which result in their retrieval. This is particularly dangerous to the applicant, where the web site retrieved belongs to a competitor.

| 15.51 All web sites must be treated as non-secure unless the Authority has a commercial arrangement with a service provider in order to maintain confidentiality and a secure connection to that web site is used.

45.5215.58 Consequently, extreme caution must be exercised when using the Internet as a search tool where (as in most cases) the international application has not yet been published. Where a relevant database is accessible via the Internet, but an alternative secure connection to the same database is accessible by the International Searching Authority, the secure connection must be used.

45.5315.59 Where no secure connection to a database on the Internet is available to the International Searching Authority, the search may be conducted on the Internet using generalized search terms representing combinations of features that relate to the claimed invention, which have already been shown to exist in the state of the art.

No Documents Found

Stopping Search

15.5515.61 Reasons of economy dictate that the examiner use appropriate judgment to end the search when the probability of discovering further relevant prior art becomes very low in relation to the effort needed. The international search may also be stopped when one or more documents have been found clearly demonstrating lack of novelty in the entire subject matter to which the claims are directed or to which they might reasonably be expected to be directed, apart from features the application of which would not involve an inventive step and which are instantly and unquestionably demonstrable as being well known in the field under consideration such that documentary evidence seems to be unnecessary. Accordingly, the examiner should not stop the search if lack of novelty is demonstrated for only a limited number of claimed embodiments, even though this would lead to an objection of lack of novelty in the written opinion. The examiner may continue searching if there are any outstanding issues regarding the requirement for a clear and complete description of the claimed invention so as to enable a person skilled in the art to make and use the invention through the whole of the field claimed, the requirement that the claimed invention be fully supported by the description, or the requirement of industrial applicability and these issues could be clarified by additional prior art. See paragraph 15.52. Where the document is an Internet disclosure and doubts exist with regard to its publication date (such that it is not clear if it was published before the relevant date according to Rule 64.1), the examiner should continue the search as though that Internet disclosure had not been retrieved.

Recording the Search

Rule 43.6(b), to (c)

45.5615.62 In recording the search history of the International Search, the examiner, lists the classification identification of the fields searched. If the IPC is not used for this purpose, the classification used is indicated. See paragraph 16.49. Depending on the policy of an International Searching Authority, the examiner may find it useful to record the search history in sufficient detail to allow examiners of national stage applications to fully interpret and rely upon the international search. This includes recording the details of any patent and non-patent literature searches as well as searches conducted on the Internet, including the key words and query operators, expressed as complete search queries to the extent practical,

logic employed as the basis of a text search which resulted in the discovery of prior art, or the amino acid or nucleic acid sequence employed as the basis of a sequence search and the sequence alignment corresponding to prior art cited in the international search report that was obtained from the sequence search, or the chemical structure employed as the basis of a chemical structure search or details of other non-classification or non-text searches performed. See paragraphs 16.53 to 16.62 for additional guidance on recordation of the search history. The recorded search history should also include any query used in any of the foregoing searches. Provision of the actual search query from these search histories is generally easily accomplished by direct printing of the search query from the automated system used to construct and perform the search query from a given electronic search resource. Where an electronic database is used, the name of the database should be provided; the actual search queries used may also be useful information that, depending on the policy of the International Searching Authority, may be provided and made available to examiners of national stage applications if practical. Examiners are also encouraged to record the search history to include the details of searches used to determine compliance with the requirements of novelty, inventive step, industrial applicability, support, sufficiency, or other appropriate requirements. However, unless required at the option of the International Searching Authority, there is no requirement to include all details of patent and non-patent literature searches that were performed during the search process.

Evaluating the Prior Art

15.5715.63 The examiner makes a determination of whether the claimed invention meets the standards for novelty and inventive step as set out in Chapters 12 and 13.

Matters of Doubt Regarding Relevant Prior Art

45.5815.64 Since the final decision with respect to novelty is not the responsibility of the International Searching Authority but of the designated Offices, the International Searching Authorities should not discard documents merely because of doubt as regards, for example, the exact date of publication or public availability, or the exact contents of an oral disclosure, exhibition, etc., to which such documents may refer. The International Searching Authority should try to remove any doubt that may exist and should cite the documents concerned in the international search report unless the date of publication or of public availability of the document concerned is clearly the same as, or later than, the filing date of the international application. Additional documents providing evidence in matters of doubt may be cited. Where the date of the reference is not clearly established, the examiner should cite the document as a category "L" document (see paragraph 16.75) and indicate in the search report that the exact date of publication has not been established.

45.5915.65 Any indication in a document of the date of its publication should be accepted by the International Searching Authority as correct unless evidence to the contrary shows a different publication date. If the indicated date of publication is insufficiently precise (for example, because a year or year and month only are given) to establish whether publication was before the filing date of the international application, the International Searching Authority should endeavor to establish the exact date with sufficient precision for that purpose. A date of receipt stamped on the document, or a reference in another document, which must then be cited, may be of assistance in this respect.

Excluded Subject Matter

15.6015.66 Special attention should be paid to the evaluation of prior art documents when assessing subject matter which may be excluded from the international search. If, in the Office acting as International Searching Authority, such subject matter is considered matter excluded under Article 17(2)(a)(i), the category symbol (see paragraphs 16.65 to 16.75) is assigned based on the subject matter which might reasonably be expected to be claimed by amendment. Where other claims appearing in the international application are directed to non-excluded subject matter, the assessment of subject matter which might reasonably be expected to be claimed by amendment should be made taking into account the subject

matter of the non-excluded claims. If, on the other hand, in the Office acting as International Searching Authority, such subject matter is non-excluded, the category symbol is assigned based on the claims appearing in the international application.

Selection of Citations and Identifying Most Relevant Portions

Rule 43.5(c); Section 505

15.6115.67 After completion of the international search, the examiner should select, from the documents retrieved, the ones to be cited in the international search report. These should always include the most relevant documents, which will be specially characterized in the report. Less relevant documents should only be cited when they concern aspects or details of the claimed invention not found in the documents already selected for citation. In cases of doubt or borderline cases in relation to novelty or inventive step, the examiner should readily make citations in order to give the applicant, the designated Offices and the International Preliminary Examining Authority the opportunity to consider the matter more fully.

15.62_15.68 If the International Bureau transmits a third party observation to the International Searching Authority in time to be taken into account in drawing up the international search report, any prior art referred to in the observation should also be considered for inclusion as if it had been found by the examiner as part of the search, provided that either a copy of the prior art is included or it is otherwise immediately available to the examiner. The examiner need only refer to the prior art listed in the observation if it is considered relevant for inclusion in the international search report.

Rule 43.5(c) to (e); Section 507(g)

45.63_15.69 __To avoid increasing costs unnecessarily, the examiner should not cite more documents than is necessary, and therefore when there are several documents of equal relevance, the international search report should not normally cite more than one of them. When more than one member of the same patent family is present in a search file, the examiner, in selecting from these documents for citation, should pay regard to language convenience, and preferably cite (or at least note) documents in the language of the international application. Also, due regard should be paid to the possible need of the designated Offices to translate cited documents. Therefore, the examiner should, whenever possible, identify precisely the part or passage of a cited document which is relevant by, for example, indicating also the page and paragraph or lines where the relevant passage appears.

45.6415.70 As a general rule, the examiner will select for citation only documents which are present in the search files of the International Searching Authority or to which access is readily available in some other manner; in that way no doubt will exist about the contents of the documents cited, since the examiner will generally have consulted each document cited.

Section 507(g), and (h)

45.65_15.71 However, under certain circumstances a document whose contents have not been verified may be cited, provided there is justification for the assumption that there is identity of contents with another document which the examiner has inspected and cited. Both documents should then be mentioned in the international search report. For example, instead of the document published before the international filing date in an inconvenient language and selected for citation, the examiner may have inspected a corresponding document (for example, another member of the same patent family, or a translation of an article) in a more convenient language and possibly published after the international filing date (see also paragraph 16.75). Also the examiner may assume that, in the absence of explicit indications to the contrary, the contents of an abstract of a document are contained in that original document. Also the examiner should assume that the contents of a report of an oral disclosure are in agreement with that disclosure.

45.6615.72 Before citing documents in a language with which the examiner is not familiar, the examiner should be satisfied that the document is relevant (for example, through translation by a colleague, through a corresponding document or abstract in a familiar language, through a drawing, or chemical formula in the document).

Procedure After Searching

Preparation of the International Search Report

45.6715.73 Finally, the examiner should prepare the international search report and the written opinion (see Chapters 16 and 17).

Amended International Search Reports

45.6815.74 It may happen occasionally that, after completion of an international search report, the International Searching Authority discovers further relevant documents (for example, in a later search for a related application). These should be added to the international search report up to the time of completion of the technical preparations for its publication by the International Bureau. An amended international search report should be sent to the applicant and to the International Bureau promptly. Thereafter, if within two years from the priority date of the international application the International Searching Authority should become aware of any particularly relevant document, it should amend the international search report and mark the report clearly as "amended." The International Searching Authority should then send a copy of the amended report to the applicant and another copy to the International Bureau for subsequent communication to the designated Offices and the International Preliminary Examining Authority.

Receipt of Misdirected Article 19 Amendments

Article 19

<u>15.75</u> Where the International Searching Authority, after transmittal of the international search report, receives from the applicant by mistake amendments to the claims under Article 19, it should transmit them promptly to the International Bureau, with which they should have been filed, and inform the applicant accordingly.

Supplementary International Search

15.76 Supplementary international search is an optional service offered in accordance with Rule 45*bis* by those International Searching Authorities which have decided to offer the service. It is intended as a supplement to the main international search, recognizing the fact that no search can be completely exhaustive, and is particularly relevant to the situation where the Authority conducting the supplementary international search has particular language specializations which may not be available in the International Searching Authority which conducts the main international search.

Rule 45bis.5(h), 45bis.9

15.77 Many of the details of the service provided are decided by the Authority which is to carry out the supplementary international search. The scope of the service offered may be subject to limitations and conditions, for example, limitations as to subject matter, limitations as to the number of such searches to be carried out by the Authority, and limitations as to the number of claims which will be searched. The scope is defined in an annex to the agreement between the International Bureau and the International Authority. Details are published in the *PCT Applicant's Guide*, Volume I, Annex SISA.

Requesting Supplementary International Search

Rules 45bis.1, 45bis.4

15.78 If the applicant wishes a supplementary international search to be carried out, he must submit a request to the International Bureau within 19 months from the priority date and pay the relevant fees within one month of submitting the request. It is expected that a request for supplementary international search will usually only be made after the applicant has seen and considered the main international search report, but this is not a requirement.

- 15.79 If the request is valid and all the fees and necessary additional items (translations and copies of sequence listings in electronic form) are provided, the International Bureau will, once it has received the international search report or after the expiration of 17 months from the priority date, whichever occurs first, transmit to the Authority specified for supplementary search a copy of each of the following:
 - (i) the supplementary search request;
 - (ii) the international application;
- (iii) any sequence listing furnished with the request for supplementary international search;
- (iv) any translation furnished by the applicant which is to be used as the basis of the supplementary international search;
- and, at the same time or promptly after their later receipt by the International Bureau:
- (v) the international search report and the written opinion established under Rule 43bis.1;
- (vi) any invitation by the International Searching Authority to pay additional fees referred to in Article 17(3)(a); and
- (vii) any protest by the applicant under Rule 40.2(c) and the decision thereon by the review body constituted in the framework of the International Searching Authority.

Receipt of the Request for Supplementary International Search by the Authority

Section 519

15.80 On receipt of the request for supplementary international search, the Authority promptly sends an acknowledgement of receipt of the copy of the international application to the applicant and to the International Bureau using Form PCT/SISA/506.

Rules 45bis.3(e) and 45bis.5(g)

15.81 If, whether prior to or following acknowledgement of receipt of the request for supplementary international search, the Authority finds that carrying out the search is excluded by a limitation or condition specified in the agreement between the Authority and the International Bureau, other than a limitation under Article 17(2) as applicable by virtue of Rule 45bis.5(c), the Authority considers the request not to have been submitted, in which case it notifies the applicant and the International Bureau accordingly using Form PCT/SISA/507 and refunds the supplementary search fee to the extent specified by the agreement, using Form PCT/SISA/508 to notify the repayment.

Start of Supplementary International Search

Rule 45bis.5(a)

45.69 15.82 The Authority specified for supplementary search normally starts the supplementary international search promptly on receipt of the documents indicated in items (i) to (iv) of paragraph 15.79, above. However, the Authority may, at its option, delay the start of the search until it has also received the international search report and written opinion of the International Searching Authority, or until the expiration of 22 months from the priority date, whichever occurs first.

Rule 45bis.4(f)

<u>15.70</u>15.83 If the written opinion of the main International Searching Authority is not in either English or a language accepted by the Authority specified for supplementary search, the Authority may request the International Bureau to provide a translation into English, which is transmitted within two months of the date of receipt of the request.

Withdrawal of the Request for Supplementary International Search

Rules 45bis.3(d), 90bis.3bis, 90bis.6(b-bis); Section 520

45.71/15.84 The applicant may withdraw the request for supplementary international search at any time before the transmittal to the applicant of the supplementary international search report or the declaration that no such report will be established. . Withdrawal shall be effective on receipt, within this time limit, of a notice addressed by the applicant, at his option, to the Authority specified for supplementary search or to the International Bureau, provided that, where the notice does not reach the Authority specified for supplementary search in sufficient time to prevent the transmittal of the report or declaration, the communication of that report or declaration under Article 20(1), as applicable by virtue of Rule 45bis.8(b), shall nevertheless be effected. In this case, processing of the supplementary international search should stop. There is no general obligation for the Authority to refund the supplementary search fee at this stage (the fee will be refunded by the International Bureau if the withdrawal occurs before any documents are sent to the Authority), but Authorities may offer full or partial refunds according to internal practice. Such policy may be set out in the section of the Agreement with the International Bureau under Article 16(3)(b) dealing with refunds. If the notice of withdrawal is received directly from the applicant, rather than from the International Bureau, the Authority should mark the notice with the date on which it was received and promptly transmit a copy to the International Bureau.

Basis of the Supplementary International Search

Rule 45bis.5

15.72 15.85 Although the applicant will often have had an opportunity to file amended claims under Article 19 (and sometimes under Article 34 in case a demand has been filed) by the time that the supplementary search is carried out, the supplementary search is performed on the basis of the international application as filed (or a translation thereof) so that it is easier for a truly complementary search to be performed and for the results to be considered together by the applicant or a designated Office.

Rules 13ter, 45bis.5(c)

45.7315.86 If the application contains disclosure of one or more nucleotide and/or amino acid sequences but does not contain a sequence listing complying with the relevant standard (see paragraph 4.15), the Authority may invite the applicant (with Form PCT/SISA/504) to furnish, within a fixed time limit, a sequence listing in written form and/or in electronic form complying with the standard for purposes of completion of the supplementary international search. If the applicant complies with the invitation, the Authority proceeds with the completion of the supplementary international search on the basis of the written and/or electronic forms of the sequence listing provided. Any sequence listing not contained in the international application as filed will not, subject to Article 34, form part of the international application, but will only be used as a search tool. If the applicant does not comply with the invitation within the time limit or if the response to the invitation does not comply with the standard, the Authority is not required to carry out the supplementary international search to the extent that such non-compliance has the result that a meaningful search cannot be carried out (see paragraph 15.87(i)).

Claims Excluded from Supplementary International Search

Rule 45bis.5(c)-(e)

15.87 In addition to limitation of the supplementary international search due to a lack of unity of invention (see paragraph 15.89, below), the supplementary search may exclude:

Rule 45bis.5(c)

(i) any claims which would not be the subject of international search by the Authority carrying out the supplementary search, whether for reasons of clarity, subject matter or failure to provide, after a warning and opportunity to comply, a sequence listing in an appropriate form (see paragraphs 15.12 and 15.33);

Rule 45bis.5(d), (e)

(ii) where the international search report or a declaration under Article 17(2)(a) has been established before the start of the supplementary search, any claims which were not the subject of the international search.

Rule 45bis.5(h), 45bis.9(a), (c)

- (iii) certain claims, in accordance with a limitation or condition specified in the agreement between the Authority and the International Bureau under Article 16(3)(b) (in particular limitations to the effect that supplementary international searches will not extend to any claim beyond a certain number of claims."
- 15.88 If exclusions referred to in paragraph 15.87(i) or (ii) mean that no supplementary international search report will be established, the Authority so declares and promptly notifies the applicant and the International Bureau using Form PCT/SISA/502. On the other hand, if some claims are excluded, but a supplementary search report is nevertheless established, the limitations are indicated in Box No. II of the supplementary international search report (Form PCT/SISA/501).

Unity of Invention

Rules 45bis.5(b), 45bis.6

15.89 Contrary to Unlike the case for the main international search, no opportunity is offered to pay additional fees in case it is found that the international application lacks unity of invention. Rather, the supplementary international search report is immediately established on those parts of the international application which relate to the main invention. Normally, this will mean the invention first mentioned in the claims. However, the examiner should also consider the following in determining whether there is unity of invention and, if so, what is considered to be the main invention:

Rule 45bis.6(b)

(i) though not bound by the views of the International Searching Authority, due account should be taken of any opinion on unity of invention included in the documents indicated in items (vi) and (vii) of paragraph 15.79;

Rule 45bis.6(f)

- (ii) if the International Searching Authority has found a lack of unity of invention, the applicant may, under Rule 45bis.1(d) have specified a wish that the supplementary search be limited to one of those inventions (for example, because the first invention is clearly not novel and he does not wish to pursue it further) if the examiner agrees with the assessment of unity of invention and the relevant claims are not excluded for any reason, the supplementary international search should focus on that invention;
- (iii) where the invention first claimed would not be searched for any reason, the first searchable invention should be considered instead;
- (iv) if other inventions are easily searched, it may be appropriate to include those inventions within the scope of the supplementary search report (see paragraph 10.64).

Rule 45bis.6(a)(ii

15.90 The examiner's opinion on unity of invention and the consequent scope of the supplementary international search should be reported on the supplementary international search report in the same a similar way as for the main international search (see paragraphs 10.83 to 10.86).

Rule 45bis.6

15.91 The normal protest procedure (see paragraphs 10.66 to 10.70) does not apply to requests for supplementary international search. However, the applicant may, within one month of the date of notification of the supplementary international search report, request the Authority to review the examiner's opinion on unity of invention. This request may be subject to a review fee. The results of the review are promptly notified to the applicant and copied to the International Bureau using Form PCT/SISA/503. The copy to the International Bureau

should be accompanied by a copy of the applicant's request for review in case this needs to be transmitted to designated Offices (see paragraph 15.92).using Form PCT/SISA/503. If the examiner's opinion is found to be at least partly unjustified, the Authority should issue a corrected supplementary search report, stating the revised view on unity of invention and, where appropriate, including the search results for all claims which should have been included. If the opinion was entirely unjustified, the applicant should also have any review fee refunded. See paragraphs 10.87 and 10.88.

Rule 45bis.6(e)

15.92 If the applicant so requests, the International Bureau will communicate the text of both the request for review and the decision thereon to the designated Offices together with the supplementary international search report.

Extent of Search

Rule 45bis.5(f)

15.93 The minimum extent scope of a supplementary search is set out in the agreement between the International Bureau and the Authority specified for supplementary search. This may be different from the PCT minimum documentation under Rule 34 since it is expected that the main international search should, subject to the language related exceptions in paragraph (e) of that Rule, cover that documentation effectively. Where the main international search report is not received before the start of the supplementary international search (see paragraph 15.82), the examiner may need to make assumptions about the scope which the main international search will have in order to decide the extent of the search which he should conduct. Any comments on this matter may be recorded on the supplementary international search report (see paragraph 15.96).

Establishment of the Supplementary International Search Report

Rule 45bis.7(a)

15.94 The supplementary international search report (Form PCT/SISA/501) must be established, or declaration that no such report shall be established (Form PCT/SISA/502) must be made, within 28 months from the priority date and transmitted to the applicant and to the International Bureau using Form PCT/SISA/505.

Rule 45bis.7(b)

The report or declaration is made in a language of publication: normally either the language of publication of the international application, or else the language of the translation provided for the purpose of the supplementary international search, though there may be cases where the first is not a language accepted by the Authority and the second is not a language of publication.

Rule 45bis.7(c)-(e)

- 15.96 The contents of the supplementary international search report are essentially the same as for the main international search report, except for the following:
- (i) an indication should be given on the cover sheet of whether the examiner was able to take into account the main international search report;
- (ii) the examiner does not classify the international application or make any indication of its classification on the supplementary international search report;
- (iii) <u>it is not necessary to include the citation of any document cited in the main international search report, unless it is considered to have additional relevance when cited in conjunction with other documents not cited in the main international search report:</u>
- (iv) explanation may be included with regard to the citations considered to be relevant: this is to allow short comments to be included to indicate what the relevant features of a document are in view of the fact that no additional written opinion is established and citations may frequently be in a language not easily understood by the applicant-the

explanation is not intended to be a full explanation of the document's relevance to novelty and inventive step of the sort expected in a written opinion;

(v) explanation may be included with regard to the scope of the supplementary international search, for example to indicate any assumptions made relating to the appropriate scope of search where the main international search report was not established and transmitted to the Authority specified for supplementary search in time to be considered during the search, or in the case of complex applications where a fallback position has been searched.

Copies of Documents

Rule 45bis.7(c)

15.7415.97 The Authority must provide copies of cited documents to the applicant or any designated Office, subject to the payment of any relevant fees, on request at any time within seven years from the international filing date, as would be the case for the International Searching Authority under Article 20(3) and Rule 44.3. Form PCT/SISA/509 may be used for this purpose.

Chapter 16 International Search Report

General

16.01 The results of the international search are recorded in the international search report (Form PCT/ISA/210), which is transmitted with Form PCT/ISA/220 to the applicant and with Form PCT/ISA/219 to the International Bureau, together with the written opinion of the International Searching Authority, which must be established at the same time. The search report is published by the International Bureau and serves as a basis for the written opinion of the International Searching Authority, any international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty), and any examination of the international application by the designated Offices or by the International Preliminary Examining Authority.

The examiner is responsible for seeing that the international search report is drawn up in such a way that it can subsequently be typed or printed in final form.

Supplementary International Search

The guidelines in this chapter also apply to the preparation of supplementary international search reports (see also paragraphs 15.94 to 15.97). For such reports, Form PCT/SISA/501 is used instead of Form PCT/ISA/210. For the covering letters, Form PCT/ISA/505 is used instead of Form PCT/ISA/220. Otherwise, specific details are only included where the required content or procedure differs from that in the case of a normal international search report. The supplementary international search report is not accompanied by a written opinion, but may include certain explanations which might otherwise have been included in a written opinion (see paragraph 15.96).

International-Type Search

16.04 The guidelines in this chapter also apply to the preparation of international-type search reports (see paragraph 2.22). For such reports, Form PCT/ISA/201 is used instead of Form PCT/ISA/210. Form PCT/ISA/220 (see paragraphs 16.14 to 16.21) is not used as a covering letter: the nature of any alternative depends on the arrangements between the International Searching Authority and the national Office on whose behalf the international-type search is conducted, as does the matter of whether the international-type search report is accompanied by a written opinion.

Time Limit for Establishing the International Search Report

Articles 17(2), 18(1); Rule 42.1

46.0216.05 The international search must be carried out in time to allow the final establishment of the international search report or of a declaration under Article 17(2) (see paragraph 9.40) before the expiration of three months from the receipt of the search copy by the International Searching Authority, which is notified to the applicant on Form PCT/ISA/202, or nine months from the priority date, whichever time limit expires later. If, in case of lack of unity of invention or of an invitation to file a sequence listing, the time limit cannot be met, the international search report is established promptly after the receipt of additional search fees or after the expiration of the time limit for payment of such fees, if no such payment is made, or after the receipt of the sequence listing.

Completing the International Search Report

Sections 110, 504, 503, 504, 505, 507, 508; Al Annex B 16.03 16.06 The following paragraphs contain information which is necessary to enable the examiner to complete the Form correctly. Further information is contained in the following Sections of the Administrative Instructions:

- (i) for the indication of dates: Section 110:
- (ii) for the classification of the international applications: Section 504 (does not apply to supplementary international search reports);

- (iii) for the identification of the cited documents: Section 503;
- (iv) for the indication of special categories of documents: Sections 505 and 507;
- (v) for the indication of the claims to which cited documents are relevant: Section 508:
- (vi) for the consideration of unity of invention: Annex B to the Administrative Instructions.

Matter Not Required by the Form

Rule 43.9, 45bis.7

46.0416.07 __The international search report must contain no matter other than as required by the Form; in particular, it must contain no expressions of opinion, reasoning, arguments or explanations. However, in the case of supplementary international search reports (which are not accompanied by written opinions), the report may contain explanations with regard to the citations and the scope of the search: see paragraph 15.96 items (iv) and (v).

(e) Different Types of International Search Reports

Articles 15(5), 16(1)

16.06 The International Searching Authority may draw up the following types of search reports:

- (i) international search report;
- (ii) international-type search report (see paragraph 2.20).

Form and Language of the International Search Report

International Search Report Form

Section 507(g)

16.05_16.08 Following completion of the search, the examiner reconsiders the classification in the light of experience acquired during the search (this does not apply to supplementary international searches, in which no classification of the international application is made) and prepares the international search report (Form PCT/ISA/210) and the Notification of Transmittal of the ISR (Form PCT/ISA/220). Once an examiner has completed the search, there should be no delay in completing the search report. The printed international search report Form (Form PCT/ISA/210) to be transmitted to the applicant and to the International Bureau contains two main sheets ("first sheet" and "second sheet") to be used for all searches. These two main sheets are intended for recording the important features of the search such as the fields searched and for citing documents revealed by the search. The printed international search report Form form also contains five six optional continuation sheets for use where necessary. There are continuation sheets for each of the "first sheet" and the "second sheet":

- (a) "continuation of first sheet (1)," "continuation of first sheet (2)," and "continuation of first sheet (3);" and
- (b) "continuation of second sheet," and "patent family annex," and "extra sheet", respectively.
- The "continuation of first sheet (1)" is used only when the international application includes a nucleotide and/or amino acid sequence and indicates the basis on which the international search was carried out, since the relevant listings or related tables may be filed or furnished at different times and in different forms. The "continuation of first sheet (2) is used where an indication is made on the first sheet that claims were found unsearchable (item 2) and/or that unity of invention is lacking (item 3). The relevant indications are then made on that continuation sheet. The "continuation of first sheet (3)" contains the text of the abstract where an abstract or an amended abstract is established by the International Searching Authority (item 5) and an indication to that effect is made on the first sheet. The

"continuation of second sheet" is to be used where the space on the second sheet is insufficient for the citation of documents. The "patent family annex," or alternatively a blank sheet, may be used for the indication of the members of patent families. The Form also includes an "extra sheet," which may be used whenever additional space is required to complete information from the other sheets. A sheet may be in paper form or may consist of the electronic equivalent of a paper sheet.

16.10 "Continuation of first sheet (3)" does not appear in the Forms for international-type searches (Form PCT/ISA/201) and supplementary international searches (Form PCT/SISA/501), which do not provide for establishment of an abstract. Form PCT/SISA/501 also contains a further optional sheet for information on the scope of the supplementary international search (see paragraphs 15.88 and 16.56).

Language of Search Report

Rule 43.4

- 16.11 The international search report is drawn up in the language in which the international application to which it relates is to be published, provided that: or,
- (i) if a translation into another language was transmitted under Rule 23.1(b) (see paragraph 15.14) and the International Searching Authority so wishes, in the language of that translation; or, =
- (ii) if the international application is to be published in the language of a translation furnished under Rule 12.4 which is not accepted by the International Searching Authority and the Authority so wishes, the international search report and any declaration made under Article 17(2)(a) may be in a language which is both a language accepted by that Authority and a language of publication referred to in Rule 48.3(a).

Supplementary international search reports are drawn up in a language of publication. Normally, this will be either the language in which the international application is actually to be published, or else the language of the translation provided for the purpose of supplementary international search, but it is possible that the former may not be a working language of the Authority and that the latter may not be a language of publication; in this case, any language of publication may be used.

Sheets Included in the Pamphlet Publication

46.0616.12 It is to be noted that only the "second sheet," the "continuation of second sheet" (if any), the "continuation of first sheet (2)" (if any), and "the extra sheet" (if any), as well as any separate sheet with information on members of patent families, will be the subject of international publication, as the "first sheet" and the continuations of first sheet (1) and (3) (if any) contain only information which will already appear on the front page of the pamphlet publication.

International-Type Search

Rules 45bis.8(bd), 94.1(a)

16.07
16.13 Any supplementary international search report is not included in the published international application, but the complete document (including the first sheet and any continuation sheets) is made available to the public, together with a translation into English where appropriate. The report is also communicated to all designated and elected Offices whenever the main international search report is requested. 16.11 If an international type search has been carried out, Form PCT/ISA/201 is used for the report.

Filling Out the Notification of Transmittal of the International Search Report of the Declaration, and the Written Opinion of the International Searching Authority (Form PCT/ISA/220)

Address for Correspondence

Section 108

| 16.0816.14 The address for correspondence is taken from the request Form form (PCT/RO/101). When an agent represents the applicant, the address for correspondence is listed in Box No. IV of the PCT request Formform. For applicants processing their own applications, the address for correspondence may be listed in Box No. II of the request Formform. However, where the correspondence on file shows any changes in the applicant or address for correspondence, the later address is used.

Applicant's or Agent's File Reference

Section 109

| 16.0916.15 The applicant's or agent's file reference is taken from the request Form (PCT/RO/101) or else the most recent file reference from the latest correspondence from the applicant or the agent.

International Application Number

<u>16.10</u>16.16 The international application number is allocated and recorded on the request <u>Form form by the receiving Office.</u>

International Filing Date

16.11 The international filing date is assigned by the receiving Office upon receipt of the international application. This date is recorded on the request Formform.

Applicant

Section 105

46.1216.18 When there is more than one applicant in respect of the international application, only the first mentioned of these on the request Form_form is indicated in the international search report. The other applicants, if any, are indicated by the words "et al" (or ET-AL) following the first applicant's name. The first mentioned applicant is indicated in Box No. II of the request Formform, a second applicant is listed in Box No. III; further applicants are listed on the continuation sheet if there are more than two applicants.

Example (i): AMERICAN TECHNOLOGIES INC. et al.

Example (ii): SMITH, John Doe

Notes:

- (a) As shown above, company names are written in capital letters; for personal names the family name is given first in capital letters and the given names are in mixed case-this helps to identify the family name.
- (b) These guidelines will be followed, *mutatis mutandis*, when the international search report is being prepared in a language, such as Japanese, that does not discriminate between uppercase and lowercase characters or when the language of the international search report has a different order of indicating surnames and given names.

Cases Where No. or Limited, Search Report is Established

Rules 39 and 67

- <u>16.13</u>16.19 No International Searching Authority is required to search or examine an international application to the extent that its subject matter is any of the following:
 - (i) scientific and mathematical theories,

- (ii) plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes,
- (iii) schemes, rules or methods of doing business, performing purely mental acts or playing games,
- (iv) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods,
 - (v) mere presentations of information,
- (vi) computer programs to the extent that the International Searching Authority is not equipped to search prior art concerning such programs.

Chapter 9 deals in detail with these exclusions from the search and examination, as well as other situations, such as lack of clarity, where it may not be possible to establish a meaningful international search in respect of some or all claims. See also paragraph 15.12, which deals with the exclusion of claims as a result of non-compliance with the relevant standards for sequence listings. Supplementary international search reports may also exclude claims which were not the subject of the main international search.

- 46.1416.20 Paragraph 9.40 indicates the course of action to be taken if it is not possible to establish an international search in respect of any of the claims.
- 46.1516.21 Where the examiner finds that the claims relate to more than one invention and these inventions are not so linked as to form a single general inventive concept, the international search report may be established only in respect of the first invention and those further inventions in respect of which additional fees are paid. See Chapter 10. The additional fees may be paid under protest (see paragraphs 10.66 to 10.70).

Filling Out the International Search Report (Form PCT/ISA/210)

Earliest Priority Date

16.1616.22 The earliest priority date is given in Box No. VI of the request Form (PCT/RO/101).

Total Number of Sheets

"It Is Also Accompanied by a Copy of Each Prior Art Document Cited in This Report" Box

| 16.1816.24 | If the International Searching Authority is sending out documents, this box is checked.

Basis of the Report

Nucleotide and/or Amino Acid Sequence Listings and Related Tables

<u>16.26</u> Where the application discloses any nucleotide and/or amino acid, box 1.b of the first sheet is checked and Box No. I (appearing on "continuation of first sheet (1)") indicates the form (that is, whether in paper <u>copy</u> or <u>computer readable electronic</u> form) and status (that is, whether filed with the international application or later, for the purposes of search) of the sequence listing, and any related tables, that the search was carried out on. See paragraphs 4.15 and 15.12 for further details.

Reference to Main International Search Report

In the case of supplementary international search reports, item 1.d of the first sheet indicates whether the international search report was received in time for it to be able to take it into account. If the international search report was not taken into account, it may be necessary to include an indication of any assumptions which were made as to the scope of the main international search in the Annex of Form PCT/SISA/501 concerning the scope of the supplementary international search (see paragraph 15.93).

Restriction of the Subject of the International Search

- | 16.2016.28 The report indicates whether the search was restricted or not for any of the reasons indicated below. If any such restrictions are applied, the claims in respect of which a search has not been carried out are identified and the reasons for this are indicated. The four categories where such restrictions may arise are:
 - (i) claims drawn to subject matter not required to be searched by the International Authority (see Chapter 9); in the case of supplementary international searches, see also paragraph 15.87)
 - (ii) claims in respect of which a meaningful search cannot be carried out (see Chapter 9);
 - (iii) multiple dependent claims which do not comply with Rule 6.4(a) (see paragraph 5.16);
 - (iv) lack of unity of invention (see Chapter 10).

The written opinion of the International Searching Authority will also report the relevant facts, usually for example, by way of a reference to the full explanation in the international search report.

- 46.2116.29 Where claims are not searched for any of the reasons (i) to (iii), box 2 of the first sheet of the international search report is checked. In addition, Box No. II of the international search report (on "continuation of first sheet (2)") is completed, giving the details.
- 16.2216.30 It should be noted that claims which rely, in respect of the technical features of the invention, on references to the description or drawings ("omnibus claims"; see paragraph 5.10) are searched and reported upon if they can be given a definite construction. However in the written opinion of the International Searching Authority and for the purposes of international preliminary examination, any breach of Rule 6.2(a) (no reference to the description or drawings except when absolutely necessary) may be reported in Box No. VII of the opinion or report.
- | 16.2316.31 | If the national law of the Office acting as International Searching Authority permits multiple dependent claims which do not comply with Rule 6.4(a), such claims are included in the international search and no indication is made under item 3 of Box No. II.
- | 16.2416.32 Where lack of unity has been found (see Chapter 10), check box 3 of the first sheet of the international search report (Form PCT/ISA/210) is checked. In addition, Box No. III of the international search report (on "continuation of first sheet (2)") is completed, irrespective of whether an invitation to pay additional search fees has issued. The search

report indicates the separate inventions present in the claims, whether additional search fees were requested and paid, and which claims were searched. It also indicates whether any additional search fees were accompanied by a protest. In the case of supplementary international search reports, there is no opportunity to pay additional fees and only a single invention is searched – see paragraphs 10.83 to 10.88 for the applicable process in this case.

Abstract, Title and Figure

Articles 3(2), 4(1)(iv); Rules 8, 44.2

<u>16.33</u> The international application must contain an abstract and a title. The examiner <u>conducting the main international search</u> indicates approval or amendment of the text of the abstract, the title of the invention, and the selection of the figure that is to accompany the abstract in items 4 to 6 of the first sheet of the international search report. Box No. IV (on "continuation of first sheet (3)") is used to record any new or amended abstract.

16.25
16.34 This procedure does not apply to supplementary international searches.
Consequently paragraphs 16.35 to 16.51 do not apply to supplementary international search reports. For international-type searches, it is a matter for agreement between the International Searching Authority and the national Office on whose behalf the international search is conducted whether the title and abstract are reviewed by the International Authority. Form PCT/ISA/201 does not include specific space for such matters; if required, the appropriate information should be recorded on separate sheets.

Abstract

Article 14(1)(a)(iv)_and (1)(b); Rules 26, 38.1 16.2616.35 Where the international application lacks an abstract, the relevant receiving Office should find this in their routine check and issue the invitation to correct accordingly, allowing at least one month from the mailing date of the invitation for a reply. The receiving Office should notify the International Searching Authority that the invitation has been sent. The receiving Office may declare the international application withdrawn if no abstract is furnished to the receiving Office within the time limit fixed. However the International Searching Authority proceeds with the international search unless and until it receives notification that the application is considered withdrawn.

Article 3(3); Rule 8.3

16.27_16.36 In determining the definitive contents of the abstract, or establishing the text of the abstract anew, where it is missing, the examiner should take into consideration the fact that the abstract is merely for use as technical information and, in particular, must not be used for the purpose of interpreting the scope of the protection sought. The abstract should be drafted so that it constitutes an efficient instrument for the purpose of assisting the scientist, engineer or researcher in searching in the particular technical field and should in particular make it possible to assess whether there is need for consulting the international application itself. WIPO guidelines for the preparation of abstracts are found in WIPO Standard ST.12/A.

Rule 8.1(a), 8.3

- 46.2816.37 In considering the adequacy of the applicant's abstract and figure, because of practical difficulties experienced by the International Bureau with publication, examiners when assessing or drafting abstracts, should have particular regard to the following:
- (a) It is important that the abstract be as concise as the disclosure permits (preferably 50 to 150 words if it is in English or when translated into English). Within this constraint the abstract must provide a summary of the technical information about the disclosure as contained in the description, claims and drawings. It should be drafted so as to serve as an efficient scanning tool for searching purposes in the art.
- (b) Phrases should not be used which can be implied, such as, "This disclosure concerns", "The invention defined by this disclosure" and "This invention relates to".

Rule 8.2(b)

- (c) Only one figure should normally be selected unless this would lead to inadequate disclosure. The inclusion of more than two figures should not be considered except in extreme circumstances where necessary information cannot be otherwise conveyed. Where none of the figures is considered useful for the understanding of the invention (even where the applicant has suggested a figure), no figure should be selected.
- (d) Abstracts may be incomprehensible if the numerals on the selected figure(s) do not correspond with those in the abstract.
- (e) An absence of reference numerals on the figures must be accepted as the examiner has no mechanism to initiate their provision.

Rule 8.1(d)

(f) Each main technical feature mentioned in the abstract and illustrated by a drawing should be followed by a reference sign, placed between parentheses.

Rule 38.2(a)

- 46.2916.38 If the international application does not contain an abstract and the International Searching Authority has not received a notification from the receiving Office to the effect that the applicant has been invited to furnish an abstract, or if the said Authority finds that the abstract does not comply with Rule 8, it establishes an abstract itself.
- <u>16.30</u> The review of the abstract should be conducted in a way that does not impact upon the date of actual completion of the search. This review should be completed in parallel with other steps in the process.
- | 16.3116.40 The applicant can only comment on the abstract prepared by the examiner after it has been established in the international search report (see search report Form PCT/ISA/210, first sheet, item 5). This is the only invitation to comment issued to the applicant. It occurs either when no abstract has been filed or when the originally filed abstract does not comply with Rule 8, and the examiner must prepare a compliant abstract. In this event the examiner establishes an appropriate abstract.

Rule 38.2(b)3

- 46.32 16.41 __The applicant is allowed one month from the date of mailing of the international search report to respond to the examiner's abstract in the report by filing at the International Searching Authority proposed modifications of the abstract, or, where the abstract has been established by the Authority, proposed modifications of and/or comments on that abstract. The Authority shall decide whether to modify the abstract accordingly, and shall notify any modification to the International Bureau.
- <u>16.33</u>16.42 If the applicant does comment, the examiner takes the applicant's comments into consideration. It is not necessary for the examiner to reply to the applicant's comment even if adverse.

Rule 38.2(b)3; Section 515

<u>16.34</u>16.43 If the International Searching Authority amends the abstract established in the international search report it notifies the International Bureau and the applicant using Form PCT/ISA/205.

- Title

Rules 4.3, 26.1, 37.2, 44.2

- - (a) personal names or trade names 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.-"

Article 14(1)(a)(iii)_and 14(1)(b); Rules 26_and 37.1 16.36_16.45 Where the international application lacks a title, the relevant receiving Office should find this in its routine check and issue the invitation to correct accordingly, allowing at least one month from the mailing date of the invitation for a reply. The receiving Office should notify the International Searching Authority that the invitation has been sent. The receiving Office may declare the international application withdrawn if no title is furnished to the receiving Office within the time limit fixed. However, the International Searching Authority proceeds with the international search unless and until it receives notification that the application is considered withdrawn.

Rule 37

16.37 16.46 The examiner is required to draft a title where:

- (i) the applicant has not responded to the invitation from the receiving Office to provide a title within the time allowed, but the International Searching Authority has not received notification that the application is considered withdrawn,
- (ii) no title was filed and the receiving Office omitted to invite the applicant to rectify the deficiency, or
- (iii) the title is deficient because it does not comply with the requirements of Rule 4.3.
- | 16.3816.47 The examiner is not required to gain the approval of the applicant for the title and the establishment of the title by the examiner is by suitable completion of the international search report Form (see check box 4 of the first sheet of Form PCT/ISA/210).
 - Drawings to Be Published
 - 16.3916.48 When indicating the Figure No. of the drawings, the applicant's suggestion is found at Box No. IX of the request Form (PCT/RO/101).
 - 46.4016.49 Where none of the figures is considered useful for the understanding of the abstract, this is indicated at the appropriate box (item 6, first sheet of the international search report).
 - 46.4116.50 When no drawings accompany the application none of the boxes are checked.
 - 46.4216.51 __It is not recommended to select more than one figure; however, if it is necessary to do so then the wording of the Form should be changed to reflect the change from single case to plural case. For example, "figure" is changed to "figures", "is" to "are" and "No." to "Nos.". (These recommendations will be followed, *mutatis mutandis*, when the international search report is being prepared in a language, such as Japanese, that does not have distinction between singular and plural forms.)

Classification of Subject Matter

Rule 43.<mark>63</mark>(a)

46.4316.52 The International Searching Authority conducting the main international search assigns obligatory "invention information" International Patent Classification (IPC) symbols in accordance with the rules as set forth in the Guide to the IPC and in the IPC itself (using the edition of the IPC in force at the time) and records this information in Box A of the second sheet of the international search report. Non-obligatory IPC symbols, as defined in the Guide (such as the optional IPC indexing codes), do not need to be applied. The IPC Guide can be accessed via the WIPO web site at: www.wipo.int. See Chapter 7. No additional classification or reclassification is made during any supplementary international search.

Fields Searched

Rule 43.6(a)

<u>16.4416.53</u> The international search report lists the classification identification of the fields searched in Box B of the second sheet of the international search report. If the IPC is not used for this purpose, the classification used is indicated.

Minimum Documentation Searched

16.4516.54 The International Searching Authority consults the minimum documentation specified in Rule 34 and considers other relevant databases or other search resources such as those listed in the Search Guidance IPDL. Where the IPC classification terms were searched, with or without restricting the search by using key words, the examiner should enter the associated IPC symbols on the international search report.

Documentation Searched Other Than Minimum Documentation

Rule 43.6(b)

- 46.4616.55 Where documentation other than the PCT minimum documentation is searched, the other documentation searched is identified in Box B of the second sheet of the international search report when practicable. This section is used for non-electronic databases searched, for example, paper or microfilm. It is used for example, for:
- (a) Capri-enter "CAPRI" and the appropriate IPC code for the classification searched, for example, "CAPRI: IPC F16B 1/02".
- (b) Search of patent specifications not forming part of the minimum documentation according to a classification system peculiar to the country issuing the patent enter classification searched, for example, "AU Class 53.6"
- (c) Search of patent specifications not forming part of the minimum documentation according to the IPC: enter the IPC codes for the classification places searched, for example, "AU: IPC B65G 51/-"

Rule 45bis.7(e)(ii)

16.56 In the case of a supplementary international search report, depending on the scope of service which is defined in the agreement between the International Bureau and the particular International Searching Authority, the examiner may assume that the PCT minimum documentation had been included in the main international search and that the main focus of the search might lie elsewhere, for example on disclosures in particular languages in which the International Authority specified for supplementary search specializes. An extra sheet may be included to make longer comments on the scope of the supplementary international search, including any assumptions which have been made on the scope of the main international search in the event that this was not received by the Authority in time to review it prior to carrying out the supplementary search (see paragraph 15.93).

Electronic Database Consulted

Rule 43.6(c)

impractical to record the exact query or queries, then a summary of the query or queries should be included. See paragraph 16.59.

| 16.4916.59 Where keywords (search terms) are used, it may be useful to include the keywords on the search report. If the number of keywords used is large, then a representative sample of the keywords could be used (for example, "Keywords: A, B, C, and similar terms"). However, depending on the policy of an International Searching Authority, the examiner may find it useful to record the search history in sufficient detail to allow examiners of national stage applications to fully interpret and rely upon the international search. See paragraph 15.62.

<u>16.50</u>16.60 Structure searches are not conveniently indicated on the search report. If a structure search was carried out this can be indicated by a statement such as "structure search carried out based on the quinoline nucleus in formula (I)".

16.5116.61 Sequence searches should be dealt with in the same way as structure searches ("search of SEQ ID 1-5").

Examples:

DWPI & keywords: A, B, C, and similar terms (Note; DWPI includes WPAT, WPI, WPIL)

JAPIO & keywords: A, B, C, and similar terms

MEDLINE & keywords: A, B, C, and similar terms

DWPI IPC A01B 1/- & keywords: A, B, C

CA & WPIDS: IPC C07D 409/- & keywords: A, B, C

CA: Structure searched based on Formula (I)

ESP@CE keywords: A, B, C.

Genbank: Sequence search on nucleic acid sequence SEQ ID NO: 1.

Notes:

- (a) Merely putting "keywords searched" without specifying the actual keywords used is not acceptable.
- (b) There is no need to indicate the way the database was accessed, for example, there is no need to specify that ESP@CE was accessed via the Internet, or MEDLINE via STN.
- (c) Where the search is conducted using a particularly relevant portion of a longer referenced nucleic acid or amino acid sequence, rather than the full length sequence referenced as filed for a particular SEQ ID NO of the sequence listing, the search examiner should indicate the region or regions of the full length reference sequence which encompassed the sequence searched. For example "search of SEQ ID NO: 1 for nucleotides 1150-1250 only."

Previous Search

| 146.5216.62 | Where the international search report is entirely or partly based on a previous search made for an application relating to a similar subject, the previous application number and the relevant search history consulted for this previous search is, where appropriate, identified as having been consulted for the international application in question, except in those instances where the details of an earlier search cannot be ascertained, or whenever it is impractical to record the full details of the earlier search. In the latter case, a summary of the earlier search should be included. Where the previous application has been published, this information is recorded in the international search report; if the previous application has not yet been published and, if the applicant is the same as that of the previous application, the information may be sent to the applicant informally when the international search report is

transmitted. if the applicant is the same as that of the previous application. See paragraph 16.59.

Documents Considered to Be Relevant

Rule 43.5

16.5316.63 The completion of Box C of the second sheet of the international search report can be considered as having three components. These are: the citation category; the citation of the document together with identification of relevant passages where appropriate; and the identification of relevant claim numbers. These three components are discussed separately in paragraphs 16.65 to 16.75, 16.78, 16.77 and 16.80, respectively, below.

16.5416.64 Some general points to note are:

Rule 33.1

- (a) Documents selected for citation should be the prior art that is closest to the applicant's invention. The duplication of teachings by way of citation of multiple documents showing the same inventive elements should be kept to a minimum (see paragraphs 15.67 and 15.69).
- (b) When citing a document, the examiner should clearly indicate which portions and specific pages of the document are most relevant (see paragraph 15.69).
- (c) In the case of supplementary international searches, the examiner need not include in the report the citation of any document cited in the international search report, except where the document needs to be cited in conjunction with other documents that were not cited in the international search report. Noting that the supplementary search is intended to supplement the main international search rather than to make a reassessment, inclusion of such citations and reassessment of their relevance should be avoided. Usually, the reason for including such a citation is where it is necessary to cite the document as category "Y" (see paragraph 16.68) to indicate a lack of inventive step when the disclosure of the document is taken together with that of a newly discovered citation, further to any lack of inventive step indicated in the main international search report. Nevertheless, recitation of a document may also be appropriate where the main international search report has clearly failed to recognize the extent of a document's relevance, for example because the first examiner was relying on an abstract or machine translation because he did not understand the original language of the document.

Citation Category

Sections 505, 507

- | 16.55 16.65 | Documents which are cited are given a category indication by way of an alphabetic character, details of which are given in Administrative Instructions 505 and 507 and below. The categories for citations are also explained under the "Documents considered to be relevant" section of the report. A category should always be indicated for each document cited. Where needed, combinations of different categories are possible.
 - Particularly relevant documents

Section 505

- 16.5616.66 Where a document cited in the international search report is particularly relevant, it is indicated by the letters "X" or "Y".
- | 16.5716.67 | Category "X" is applicable where a document is such that when taken alone, a claimed invention cannot be considered novel or where a document is such that when considered in light of common general knowledge, a claimed invention cannot be considered to involve an inventive step.
- 16.5816.68 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.

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

Section 507(c)

<u>16.59</u>16.69 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 is indicated by the letter "A".

Documents which refer to a non-written disclosure

Section 507(a)

46.6016.70 Where a document cited in the International search report refers to a non-written disclosure, the letter "O" is 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 paragraphs 16.67 to 16.69, for example O,X, O,Y or O,A.

Intermediate documents

Section 507(d)

46.61_16.71 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 Article 2(xi)(b)), are denoted by the letter "P". The letter "P" is also 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, for example P,X, P,Y or P,A.

Documents relating to the theory or principle underlying the invention

Section 507(e)

16.6216.72 Where any document cited in the search report is a document whose publication date occurred after the filing date or the priority date of the international application and is not in conflict with the said application, but 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 is indicated by the letter "T".

Potentially conflicting patent documents

Section 507(b)

46.63_16.73 __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 on or after the international filing date and the content of which would constitute prior art relevant to novelty (Article 33(2)) or inventive step (Article 33(2)) is indicated by the letter "E" (see section Section 507(b) and Rule 33.1(c)). Where the patent document and the application searched have the same date, the patent document is also identified by the letter "E" An exception is made for patent documents based on the priority under consideration.

Documents cited in the application

16.6416.74 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.

Documents cited for other reasons

Section 507(f)

| 16.6516.75 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 (Article 4(C)(4) of the Paris Convention), or
 - (b) a document cited to establish the publication date of another citation

the document is indicated by the letter "L". Brief reasons for citing the document should be given. Documents of this type need not be indicated as relevant to any particular claims. However, where the evidence which they provide 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 citation of the document should refer to those claims.

Non-prejudicial disclosures

46.6616.76 In certain cases the invention may have been disclosed, before the relevant date for the purposes of the PCT, in such a way that it is not considered to form part of the state of the art in accordance with the national law of one or more designated Offices. 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). However these exemptions do not necessarily apply in all designated Contracting States and additionally, according to Rule 51*bis*.1(a)(v), 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 international search report with the appropriate category indicated above and may also be considered in the written opinion of the International Searching Authority and during international preliminary examination.

Relationship Between Documents and Claims

Section 508

46.67_16.77 __Each citation should include a reference to the claims 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 paragraph 16.80 and "A" documents, see paragraph 16.73). It is also possible for the same document to represent a different category with respect to different claims. For example:

Χ	WO9001867 A (WIDEGREN LARS (SE))	1
	8 March 1990 (1990-03-08)	
Υ	* figure 1 *	2-5
Α	* 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 which represents non-prejudicial state of the art for the subject matter of claims 6-10.

Citation of the Documents

Section 503; WIPO Standard ST.14

- <u>16.78</u> Identification of any document should be made according to WIPO Standard ST.14. In the case of patent documents, this means the inclusion of:
- (i) the industrial property office that issued the document, by the two-letter code (WIPO Standard ST.3);
- (ii) the number of the document as given to it by the industrial property office that issued it (for Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document);
- (iii) the kind of document, by the appropriate symbols as indicated on the document under WIPO Standard ST.16 or, if not indicated on that document, as provided in that Standard, if possible;

- (iv) the name of the patentee or applicant (in capital letters and, where appropriate, abbreviated);
- (v) the date of publication of the cited patent document (using four digits for a year designation according to the Gregorian Calendar) or, in case of a corrected patent document, the date of issuance of the corrected patent document as referred to under INID code (48) of WIPO Standard ST.9 and, if provided on the document, the supplementary correction code as referred to under INID code (15):
- (vi) indications of the location of the most relevant cited material within the document, preferably by means of paragraph numbers or page and line numbers; where multiple renderings of the same document are published (for example, PDF and HTML); it may also be necessary to indicate which version of the document is being referred to (WIPO Standard ST.14 also provides recommendations for best modes of identifying passages in cases where paragraph, page and line numbers are not well defined).

Rule 45bis.7(e)(i)
16.79 In the case of supplementary international search reports, an explanation may also be included with regard to why the citation is considered relevant. This is not intended to be as full an explanation as would be made in the written opinion which accompanies the main international search report, but aims to assist the reader in establishing the reason for which a document was cited, noting especially that many citations in supplementary international search reports may be in languages which might not be fully comprehended by the applicant or by designated and elected Offices. If this explanation can be made in a few words, such that it will not make the list of citations difficult to read, it should be included together with the main citation. If a longer explanation appears necessary, a separate sheet may be added for the purpose.

- | 16.6816.80 For "A" citations it is not necessary to indicate the relevant claims unless there is good reason to do so; for example where there is a clear lack of unity *a priori* and the citation is relevant only to a particular claim or group of claims or when the claims meet the criteria of novelty, inventive step, and industrial applicability under Article 33(2) to (4) and the "A" category citations represent the most relevant prior art.
 - <u>16.6916.81</u> The box on the second sheet of Form PCT/ISA/210 entitled "Further documents <u>are</u> listed <u>are</u> in the continuation of Box C" is checked if more documents are cited than will fit in the space provided in Box C and therefore a continuation sheet is used.
- 16.7016.82 The search report is published with the specification and distributed worldwide. To enable any reader in any country to consider the citation in the most convenient document/language, the known family members of each citation are normally listed in the patent family annex sheet of the international search report. The box on the second sheet of Form PCT/ISA/210 entitled "See patent family annex" is checked if a family member listing is included with the report. Where INPADOC is used to check the family member, it should be noted that:
- (a) INPADOC does not provide family listings for documents published prior to 1968;
- (b) If INPADOC indicates there are no family members for a cited document then indicate this by entering the word "NONE" where the family members would appear. This indicates to the applicant that a search for family members has been carried out and there was a nil result; and
- (c) If INPADOC indicates that none of the citations has a family member the "See patent family annex" box should still be checked and the practice indicated in the paragraph (b) above should be followed for all citations.

Finalization of the Report

Article 19; Rules 43.1, 43.2, 46.1

16.7116.83 The identification of the International Searching Authority which established the international search report and the date on which the report was drawn up are indicated at the bottom of the second sheet of the international search report. This date should be that of the drafting of the report by the examiner who carried out the search. In addition to the date of actual completion, that is, the date on which the report was drawn up, of the international search, the international search report also indicates the date on which it was mailed to the applicant, which is important for the computation of the time limit for filing amendments to the claims under Article 19.

Rule 43.8; Section 514

46.7216.84 Where the examiner is an authorized officer his name will appear on the search report. Where the examiner is not an authorized officer the name of the responsible examiner who will be supervising the report should be entered as the authorized officer. Where the examiner is an authorized officer then the date of actual completion will be the date of completion of the search report and he enters it on the search report. Where the examiner is not an authorized officer, the "date of completion" should be entered after the responsible officer has supervised the report and corrections, if any, have been made.

16.7316.85 The report should be mailed within 3-three months of receipt of the search copy or within 9-nine months from the priority date, whichever is later.

Copies of References Cited in the International Search Report

Rule 44.3

| 16.7416.86 The International Searching Authority should preferably attach copies of all references cited to the copy of the international search report which is sent to the applicant. However, the preparation of such copies may be the subject of a separate request and payment of a separate fee for copies may be required. For the invitation for payment of fees Form PCT/ISA/221 may be used.

Article 20(3); Rule 44.3

| 16.75 16.87 The International Searching Authority or an agency responsible to it must send, upon request, copies of all references cited in the international search report to any designated Office or the applicant. Such a request may be presented any time during seven years from the international filing date under the conditions laid down in Rule 44.3. Copies of the references cited may be transmitted with Form PCT/ISA/211.

PART V WRITTEN OPINION/INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Chapter 17 Content of Written Opinions and the International Preliminary Examination Report

Introduction

17.01 This chapter covers the content of any written opinion, whether established by the International Searching Authority or the International Preliminary Examining Authority. It also covers the content of the international preliminary examination report, which follows a very similar format to a written opinion.

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

- 17.02 The purpose of a written opinion, issued by the International Searching Authority or the International Preliminary Examining Authority, is to give a primary indication to the applicant of the defects which the examiner considers to exist in the application so that the applicant can determine the most appropriate course of action, including the possibilities of filing a demand for international preliminary examination or submitting comments or amendments, before any international preliminary examination report is drawn up. Its primary role is to identify whether or not the claimed invention appears to be novel, involve an inventive step (be non-obvious) and be industrially applicable. It will also include opinions on certain other substantive defects in so far as checked by the Authority, mainly where these affect the ability to determine the novelty, inventive step or industrial application of the invention accurately, and on certain defects in the form of the international application (see Rule 43bis.1(a) and Rule 66.2(a)).
- 17.03 The international preliminary examination report follows the same format as a written opinion and, assuming that international preliminary examination is demanded, is established taking into account any amendments or observations filed in response to the written opinions (either of the International Searching Authority or of the International Preliminary Examining Authority) which precede it.

Different Types of Opinion and Report

Written Opinion of the International Searching Authority

Rule 43bis, 66.1bis

- 17.04 A written opinion will be issued by the International Searching Authority together with the international search report or the declaration under Article 17(2)(a) that no international search report will be established. This will normally be treated as the first written opinion of the International Preliminary Examining Authority under Article 34(2) in the event that international preliminary examination is demanded and, as such, the opinion will include an invitation to submit a response, together with a time-limit (see Rules 43*bis*.1(c) and 54*bis*.1(a)) for that response, if the applicant wishes to demand international preliminary examination. However International Preliminary Examining Authorities may notify the International Bureau that this will not be the case for written opinions issued by specified International Searching Authorities other than themselves. Such notifications are published by the International Bureau in the Gazette.
- 17.05 Many of the Rules that are referred to in this chapter are stated to apply to the International Preliminary Examining Authority conducting an international preliminary examination under Chapter II of the Treaty. However, while this is not explicitly stated in the references, they also apply to the International Searching Authority by virtue of Rule 43*bis*.1(b).

Written Opinion(s) of the International Preliminary Examining Authority

Rule 66.4, 66.6

- 17.06 Written opinions may also be issued by the International Preliminary Examining Authority where international preliminary examination is demanded. The written opinion of the International Searching Authority is usually treated as the first written opinion of the International Preliminary Examining Authority. Although not required, the IPEA may establish further written opinions taking into account arguments or amendments made by the applicant in response to the written opinion issued by the International Searching Authority. Such written opinions will normally offer the applicant a further opportunity to submit amendments or arguments before the international preliminary examination report is established. The International Preliminary Examining Authority may also communicate informally with the applicant over the telephone, in writing, or by personal interview.
- 17.07 For international applications where the written opinion of the International Searching Authority is not treated as the first written opinion under Article 34(2), the International Preliminary Examining Authority should (except where all the conditions (i) through (vi) set out in paragraph 19.22 apply):
- (a) establish a first written opinion as defined in paragraph 17.02, which should take into account the content of the written opinion established by the International Searching Authority; and
- (b) notify the applicant accordingly in writing and set a time period for response as defined in Rule 66.2(d).

The International Preliminary Examination Report

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

Content of the Opinion or Report

Overview of Content

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

- 17.09 Any written opinion should usually cover all matters referred to in Rule 66.2. Such matters may be:
- (i) whether any of the situations referred to in Article 34(4) apply (subject matter of the application not required to be examined by the International Preliminary Examining Authority or meaningful opinion on novelty, inventive step or industrial applicability not possible because of lack of clarity or because the claims are not adequately supported by the description),
- (ii) an apparent failure to meet the criteria of novelty, inventive step or industrial applicability,
- (iii) defects in the form or contents of the international application insofar as checked by that Authority (for example, failure to comply with one or more of the requirements specified in Rules 5 to 11),
- (iv) amendments which appear to go beyond the disclosure of the international application as filed or which do not comply with Rule 46.5(b)(iii) or Rule 66.8(a) (see paragraph 17.23) (only applicable for International Preliminary Examining Authority procedures),
- (v) an apparent lack of clarity in the claims, the description or the drawings or of support for the claims in the description such as would require some observations to be made in this respect in the international preliminary examination report should such report be

established on the basis of the international application without further amendment insofar as checked by that Authority,

- (vi) that a claim is directed to an invention on which no international search report has been established, and
- (vii) nucleotide and/or amino acid sequence listings not being available in such a form that a meaningful international preliminary examination can be carried out.

Form of Opinion or Report

- 17.10 Written opinions are established in a standard format using Form PCT/ISA/237 (for the opinion of an International Searching Authority) or PCT/IPEA/408 (for an opinion of the International Preliminary Examining Authority). International preliminary examination reports (given the title "international preliminary report on patentability (Chapter II of the Patent Cooperation Treaty)") are established using Form PCT/IPEA/409. Apart from the cover sheet, containing generally bibliographic details and any notification of action that the applicant may be invited to take, these follow the same format, including whichever of the following parts are appropriate to the particular international application:
 - (i) Basis of the opinion or report;
 - (ii) Priority;
- (iii) Non-establishment of opinion with regard to novelty, inventive step and industrial applicability;
 - (iv) Lack of unity of invention;
- (v) Reasoned statement under Rule 66.2(a)(ii) or Article 35(2) with regard to novelty, inventive step or industrial applicability and citations supporting such statement;
 - (vi) Certain documents cited;
 - (vii) Certain defects in the international application;
 - (viii) Certain observations on the international application.

Sheets which have not been filled in (blank sheets) are to be omitted from the opinion or report, and are not to be included in the total number of sheets listed under item 2 of the cover sheet.

Data

Section 109

- 17.11 The following data (insofar as set out on the cover sheet of the Form) are first included in accordance with Rules 43*bis*.1(b), 70.3, 70.4, 70.5 in the written opinion and the international preliminary examination report:
 - (i) the international application number:
 - (ii) the name of the applicant;
 - (iii) the name of the International Authority;
 - (iv) the international filing date;
- (v) the classification of the subject matter, at least according to the International Patent Classification (IPC);
 - (vi) the claimed priority date;
- (vii) the applicant's or agent's file reference (composed either of letters or numbers or both, but not exceeding 12 characters).

Section 504

17.12 The indication of the classification of the subject matter referred to in item (v), above, repeats the classification of the subject matter by the International Searching Authority given under Rule 43.3 if the examiner agrees with such classification, or, if the examiner does not agree with that classification, sets forth the classification which the examiner considers to be correct (see Chapter 7).

Box No. I: Basis of the Written Opinion

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

- 17.13 Since the written opinion of the International Searching Authority is drawn up at the same time as the international search report, it is always established on the basis of the application as filed, or a translation thereof, and subject to the possibility of sequence listings being furnished later for the purposes of international search (see paragraphs 17.15 and 17.21). (See paragraph 17.16 for a definition of "originally filed sheets.") However, any written opinion drawn up after rectifications (before the International Searching Authority and International Preliminary Examining Authority) or amendments and/or rectifications (before the International Preliminary Examining Authority) should take these into account and indicate the relevant replacement sheets in the opinion.
- 17.14 Any amendment submitted must not add subject matter which goes beyond the disclosure of the international application as originally filed (see Chapter 20).
- Language Considerations

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

- 17.15 With regard to the language, item 1 of Box No. I need not be filled if all the elements of the application (originally filed sheets and amended sheets, if any) were available or furnished to the International Authority in the language in which the international application was filed. Otherwise, an appropriate indication must be checked as to whether the elements were available or furnished to the International Authority in the language which is:
- (i) the language of a translation furnished for the purposes of international search (under Rule 23.1(b));
- (ii) the language of publication of the international application (under Rule 48.3(b)); or
- (iii) the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

For further discussions of language, refer to Chapter 18.

- Replacement Sheets Deemed to Be Part of the Application as Originally Filed
- 17.16 Replacement pages or sheets, filed in response to an invitation by the receiving Office to correct defects in the international application, are deemed to be part of the international application "as originally filed". If the applicant responds to the invitation to correct defects by replacing sheets of the application, these sheets are identified with "SUBSTITUTE SHEET (RULE 26)" stamped on them. Also, replacement pages or sheets for rectification of obvious errors under Rule 91 are deemed to be part of the international application "as originally filed". These sheets are identified with "RECTIFIED SHEET (RULE 91.4)".
- Examination on Basis of Amended International Application
- 17.17 Where a written opinion of the International Preliminary Examining Authority or international preliminary examination report is based on the international application as originally filed or furnished, this is noted by checking the first box under item 2 of Box No. I of the relevant Form. Where amendments have been filed, the report indicates the version of each page on which the opinion or report is based.

- 17.18 Where amendments under Article 19 have been made by the applicant, they should be referred to in Box No. I, item 2 as "claims: pages as amended under Art 19". Note that under Article 19 only claims may be amended. These sheets are usually identified by "AMENDED SHEET (ARTICLE 19)".
- 17.19 Where amendments under Article 34 have been made by the applicant, these should also be referred to in Box No. I, item 2 as "....pages....received by this Authority on.....".

Rule 70.16; Section 602

- 17.20 The amendments under Article 34 should indicate the dates on the amendments as the "received on" dates. Superseded amendments are not normally included. However, if a first replacement sheet is acceptable and a second replacement sheet for the same numbered sheet contains subject matter that goes beyond the original disclosure of the application as filed, the second replacement sheet supersedes the first replacement sheet, but both the first and second replacement sheets are attached to the international preliminary examination report along with the accompanying letters as required under Rule 70.16(a). In this case, the superseded replacement sheets are marked "SUPERSEDED REPLACEMENT SHEET (RULE 70.16(b))" in addition to the marks indicating when it was received as an amendment sheet. When the Annexes to the international preliminary examination report contain both final amendments, which are considered to contain subject matter that goes beyond the original disclosure or which are not accompanied by a letter indicating the basis for the amendments in the application as filed, and earlier amendments, which form part of the basis of the report, this fact is noted in the relevant box under item 3.a of the cover sheet to Form PCT/IPEA/409.
- Nucleotide and/or Amino Acid Seguence Listings
- 17.21 With regard to any nucleotide and/or amino acid sequence listing, one or more of the following indications must be given with respect to the sequence listing, and/or tables related thereto, on which the examination is based, either in item 2-3 of Box No. I (for the written opinion of the International Searching Authority) or in item 1 of the Supplemental Box Relating to Sequence Listings (in written opinions of the International Preliminary Examining Authority or the international preliminary examination report):
- (a) the type of material (sequence listing only or also related tables) forming part of the international application as filed (in the form of an Annex C/ST.25 text file, or on paper or in the form of an image file);
- (b) furnished together with the international application under Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file; format of material (written or computer-readable form); and
- (b)(c) furnished subsequent to the international filing date for the purposes of international search and/or preliminary examination (in the form of an Annex C/ST.25 text file, or on paper or in the form of an image file); and (in the case of international preliminary examination)
- (c)(d) furnished as an amendment under Article 34 (in the form of an Annex C/ST.25 text file, or on paper or in the form of an image file) the time of filing or furnishing (contained in the application as originally filed, filed together with the international application in computer-readable form, subsequently furnished for the purposes or search and/or examination, or filed as an amendment).

Where more than one version or copy of a sequence listing and/or table related thereto has been filed, the check box under item 2 (or item 3-4 of Box No. 4-1 of the written opinion of the International Searching Authority) is used to indicate whether the required statements were included, that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed. For further discussions of the nucleotide and/or amino acid sequence listings, refer to Chapter 18.

- Amendments Resulting in Gaps in Numbering
- 17.22 Where amendments under Article 19 or 34 have been made which result in cancellation or gaps in the numbering sequence of the description pages, claim numbers, and/or drawing sheets, these are detailed in item 3 of Box No. I of the written opinion and/or report.
- Amendments Going Beyond Original Disclosure

Rule 70.2(c)

- 17.23 Where amendments have been made which go beyond the original disclosure of the application as filed, the examiner identifies said amended sheet(s) in item 4 of Box No. I of the written opinion of the International Preliminary Examining Authority or the international preliminary examination report. The particular amendments are identified and brief reasons given in a Supplemental Box sheet. These amendments are attached to the international preliminary examination report as Annexes, in addition to any amended sheets which form part of the basis of the report. (See also paragraph 17.20)
- 17.24 Refer to paragraph 20.11 for further Article 19/34 considerations.
- Top-up Searches

Rule 70.2(f)

17.25 With regard to top-up searches, the appropriate indication must be given in item 6 of Box No. I of the report with respect to whether a top-up search has been carried out by the International Preliminary Examining Authority. Where it has carried out a top-up search, the examiner also indicates the date on which the top-up search was carried out and whether additional relevant documents have been discovered during the top-up search.

Amendments Not Accompanied by a Letter to Indicate Explain Their Basis in the Application as Filed

Rule 70.2(c-bis)

17.26 Where amendments have been made but the replacement sheet or sheets was not accompanied by a letter indicating the basis for the amendment in the application as filed and the report is established as if the amendment had not been made, the examiner identifies said amended sheet(s) in item 4 of Box No. I of the written opinion of the International Preliminary Examining Authority or the international preliminary examination report. These amendments are attached to the international preliminary examination report as Annexes, in addition to any amended sheets which form part of the basis of the report. (See also paragraph 17.20)

Rectification of Obvious Mistakes

Rule 70.2(e); Section 607

17.27 If a rectification of an obvious mistake is taken into account under Rule 66.1, the report shall so indicate in tem 5 of Box No. 1 of the written opinion of the International Preliminary Examining Authority or the international preliminary examination report. If a rectification of an obvious mistake is not taken into account pursuant to Rule 66.4bis, the report shall, if possible, so indicate in item 5 of Box No. 1 of the written opinion of the International Preliminary Examining Authority or the international preliminary examination report, failing which the International Preliminary Examining Authority shall notify the International Bureau accordingly and the International Bureau shall proceed as provided for in the Administrative Instructions.

Box No. II: Priority

17.2517.28 This part of the opinion or report is not relevant if the international application does not claim priority. Furthermore, where priority is claimed, but the citations in the

international search report were all published before the earliest priority date, it is not necessary to consider whether the priority claim is valid (see Chapter 6). In either of these cases, this Box should not normally be included in the opinion or report.

- 47.2617.29 Where one or more citations of the international search report were published after the earliest priority date, the validity of that earliest priority date requires checking (see paragraph 6.03 for formal requirements and paragraph 6.05 for substantive requirements).
- (a) Where the priority document is one which is in the records of the International Authority, it should be obtained from those records.
- (b) If a copy of the priority document (or a necessary translation) is not available before preparation of the written opinion of the International Searching Authority because it has not yet been provided by the applicant, and if that earlier application was not filed with that Authority in its capacity as a national Office or the priority document is not available to that Authority from a digital library in accordance with the Administrative Instructions, the written opinion of the International Searching Authority may be established as if the priority had been validly claimed and this fact is noted in item 1 of Box No. II.
- (c) Where the priority document is provided by the applicant in compliance with Rule 17.1 after the preparation of the search report and the written opinion of the International Searching Authority, any written opinion of the International Preliminary Examining Authority and/or the international preliminary examination report should reconsider the validity of the priority claim.

Rule 66.7; Section 421

(d) Where the priority document is a foreign document and it is not already in the file, the International Authority may request a copy of the document from the International Bureau and, if necessary, a translation from the applicant. In the meantime, if the outcome of the examination requires the issuing of an opinion, that opinion should be issued without waiting to obtain the priority document and/or the translation (see (b), above, in the case of a written opinion of the International Searching Authority). An appropriate comment should be made under the heading "Additional observations, if necessary:" in Box No. II of the written opinion. If such a copy of the priority document and/or the translation is not available because of non-compliance by the applicant with Rule 17.1 within the relevant time period, and if the priority document is not available to that Authority from a digital library in accordance with the Administrative Instructions, any written opinion of the International Preliminary Examining Authority and/or the international preliminary examination report may be established as if the priority had not been claimed and this is indicated in the report.

Rule 64.1

| 17.2717.30 Where the right to priority is invalid, item 2 of Box No. II of the written opinion or international preliminary examination report must be completed.

47.2817.31 "Additional observations" in item 3 of Box No. II relate to Priority considerations only and not to clarity, descriptive support, defects or any other consideration relevant to Box No. VIII. Such observations might include the reasons for which a priority claim was considered to be invalid, or else an indication that the priority claim had been checked and was considered to be valid.

Box No. III: Non-Establishment of Opinion with Regard to Novelty, Inventive Step and Industrial Applicability

Article 17(2)(a)(i); Rules 43bis.1, 67

| 17.2917.32 This part of the opinion or report explains why an opinion as regards novelty, inventive step and industrial applicability may not have been established for some or all of the subject matter of the international application—for any reason other than because the international application lacks unity of invention and the required additional fees have not been paid (this is dealt with in Box No. IV, see paragraphs 17.38 to 17.41. For example, Rules 43bis.1(b) and 67.1 establish that no International Authority shall be required to

examine certain subject matter within an international application, such as mathematical theories, plant or animal varieties and methods for treatment of the human or animal body. The agreements between the International Bureau and the International Preliminary Examining Authorities further qualify this by excepting from exclusion any subject matter which is examined under the relevant national grant procedures. See paragraph 17.60 and Chapter 9 for details of excluded matter. The first two check boxes of Box No. III are used to indicate the extent to which no opinion has been established. In the written opinion of the International Searching Authority, the reasons for not establishing an opinion will usually be identical to the reasons for not establishing an international search and can, for example, usually be indicated by way of a reference to the full explanation in the international search report (see paragraph 16.28) or in the declaration under Article 17(2)(a) (see paragraph 9.40)).

Subject Matter Excluded Under Rule 67.1

47.3017.33 Where some or all claims are not examined for novelty, inventive step or industrial applicability because they contain excluded subject matter, this observation is indicated in the third check box of Box No. III of the written opinion or examination report.

Clarity or Support

Rule 66.2(a)

17.31_17.34 Where the description, the claims, or the drawings are so unclear, or the claims are so inadequately supported by the description that no meaningful opinion can be formed on the questions of novelty, inventive step, or industrial applicability of the claimed invention, then the examination may be restricted to those claims, or parts of claims, that are sufficiently clear and supported by the description to enable an opinion or report to be prepared (see Box No. III, 4th and 5th check boxes). In such a case Where an opinion cannot be established on a claim, the examiner marks the appropriate check box in Box No. III (the 4th and/or the 5th check boxes) and includes observations on lack of clarity and/or support to explain the limitation of the examination.

47.32 17.35 The issues of clarity and descriptive support of claims should, as appropriate, may be raised separately from considerations of novelty, inventive step and industrial applicability at Box No. VIII of the opinion or report (see Chapter 5 and paragraph 17.5017.48).

17.36____These matters should not be raised in an international preliminary examination report unless they have already been raised in a written opinion.

No International Search Made for Some or All Claims

Article 33(6)

47.3317.36 Where the International Searching Authority has not established an international search report and instead issued a declaration under Article 17 (relating to excluded subject matter, clarity, lack of unity, etc.), the questions of novelty, inventive step and industrial applicability cannot be addressed since there are no documents to consider under Article 33(6), and this is noted using the sixth check box of Box No. III. (Note that this applies even where Article 34 amendments may have overcome considerations under Article 34(4)(a)(ii)).

Nucleotide and/or Amino Acid Sequence Listings

Al Annexes C, C-bis

47.3417.37 A failure to supply nucleotide and/or amino acid sequence listing information, or have it comply with the Administrative Instructions standards, may preclude any meaningful preliminary examination from being carried out. Refer to Chapter 15 (search stage) and Chapter 18 (examination stage) for discussion of the nucleotide and/or amino acid sequence listings. A submission in electronic form of tables relating to the sequence listings not in compliance with the Annex C-bis of the Administrative Instructions may also

preclude any meaningful preliminary examination from being carried out (see Box No. III, item 3). In either case the The Authority should make a meaningful search or preliminary examination to the extent that it is possible, but if some or all claims cannot be examined, the reasons are noted in the final check boxes of Box No. III, and details may be provided in the Supplemental Box if necessary.

Box No. IV: Lack of Unity of Invention

Article 34(3); Rule 70.13

- 47.36_17.39 __If the applicant has paid additional fees before the International Searching Authority or the International Preliminary Examining Authority, or has restricted the claims before the International Preliminary Examining Authority in response to an invitation to do so, or if the applicant has failed to respond to the invitation to pay additional fees or restrict the claims (see paragraphs 10.74 to 10.82), this is also indicated in the opinion or report. The possible indications (some of which are not relevant to the written opinion of the International Searching Authority) are that:
- (i) the claims have been restricted before the International Preliminary Examining Authority;
 - (ii) additional fees have been paid without protest;
- <u>(iii)</u> additional fees have been paid by the applicant under protest <u>and</u>, <u>where</u> applicable, the protest fee was paid;
- (iv) additional fees have been paid by the applicant under protest but the applicable protest fee was not paid;
 - (iii)(v) the applicant has neither restricted the claims nor paid additional fees;
- (iv)(vi) (v) the examiner was of the opinion that the international application did not comply with the requirement of unity of invention but decided not to issue an invitation to restrict the claims or pay additional fees.
- <u>17.37</u>17.40 In addition, the final item of Box No. IV indicates for which parts of the international application the opinion or report was established, in view of the findings on unity and any restrictions which have been made or additional fees which may have been paid.
- Additional Fees Paid Under Protest

Rule 68.3(c); Section 603

- | 17.3817.41 In the case under Chapter II where the additional fees are paid under protest, the text of the protest, together with the decision thereon, is annexed to the international preliminary examination report if the applicant has so requested (see paragraph 10.80). For the case under Chapter I where additional fees are paid under protest, see paragraphs 10.68 and 10.70.
 - Box No. V: Reasoned Statement Under Rule 66.2(a)(ii) with Regard to Novelty, Inventive Step or Industrial Applicability; and Citations and Explanations Supporting Such Statement
 - Article 35(2); Rules 43.5(b), 66.2(a)(ii), 70.6(a) and (b), 70.7(b), 70.8; Sections 503, 611 17.3917.42 A statement as to whether the claims appear to satisfy the criteria of novelty, inventive step (non-obviousness) and industrial applicability (see paragraph 19.02) is made in item 1 of Box No. V. The examiner makes this statement in relation to each claim which is to be examined, that is, by the words "YES" or "NO," or their equivalents in the language of the report (in a written opinion of the International Preliminary Examining Authority the

examiner may only refer to those which do not appear to satisfy the criteria). Each such statement must be accompanied by relevant citations, explanations and observations, if any (see paragraph 17.09) in item 2 of Box No. V. A statement on all three of the criteria should be made. If a negative statement is made regarding lack of industrial applicability, statements should still be made regarding novelty and inventive step if at all possible. The examiner should always cite documents believed to support any negative statement with respect to any of the claimed subject matter. The citation of these documents is made in accordance with WIPO Standard ST.14.

Rules 43.5(e), 70.7(b); Section 604

17.40

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

47.41 Further guidance on the novelty considerations, inventive step consideration and industrial applicability considerations are provided in Chapter 12, Chapter 13 and Chapter 14, respectively.

Box No. VI: Certain Documents Cited

- The examiner also mentions, as such, any published application or any patent referred to in the report by virtue of Rule 64.3 and provides for each such published application or patent the following indications:
 - (i) its date of publication;
 - (ii) its filing date, and its claimed priority date (if any);

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

- <u>47.4217.46</u> If the examiner has discovered, or the international search report has cited, a relevant document which refers to a non-written disclosure, and the document was only published on or after the relevant date of the international application, he indicates in the written opinion and/or the international preliminary examination report:
- (i) the kind of non-written disclosure its nature (by placing the letter "O" next to the citation);
 - (ii) the date on which the non-written public disclosure occurred;
 - (iii) the date on which the document was made available to the public.

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

- 17.44 The examiner also mentions, as such, any published application or any patent referred to in the report by virtue of Rule 64.3 and provides for each such published application or patent the following indications:
 - (i) its date of publication;
 - (ii) its filing date, and its claimed priority date (if any);
- (iii) placing the letter "E" next to the citation.

Rule 70.2(b)

47.4317.47 The report may also indicate that, in the opinion of the International Searching Authority or the International Preliminary Examining Authority, the priority date of <u>such published application or patent is not valid</u> the international application has not been validly claimed (see also paragraph 17.29).

Rule 70.7(b)

| 17.4417.48 | Details concerning the manner of indicating certain other special categories of documents which may be cited in the written opinion and/or the international preliminary examination report as well as the manner of indicating the claims to which the documents

cited in such report are relevant can be found in Sections 507(c), (d) and (e) of the Administrative Instructions (as set out, for the purposes of the international search report, in paragraphs 16.69, 16.71 and 16.72).

Box No. VII: Certain Defects in the International Application

Rule 70.12

<u>47.45_17.49</u> If, in the opinion of the examiner, defects exist in the form or contents of the international application (for example, failure to comply with one or more of the requirements specified in Rules 5 to 11), the examiner includes this opinion in Box No. VII of the written opinion and/or examination report and also indicates the reasons therefore (see also paragraphs 17.09, 17.13 and 17.14).

Box No. VIII: Certain Observations on the International Application

Rule 70.12

47.4617.50 If, in the opinion of the examiner, there are significant and pertinent issues as to the clarity of the claims, the description and the drawings, or the question whether the claims are fully supported by the description, observations should be made as to the clarity of the claims, the description, and the drawings, or the question whether the claims are fully supported by the description, the examiner includes these observations to the effect in Box No. VIII of the written opinion and/or examination report. and also indicates the reasons therefor In such a case, the examiner should list the numbers of any relevant claims and indicate the reasons for lack of clarity and/or support. In deciding whether or not to include any observations on these matters, due account should be given to the significance and relevance of the observations in any further processing of the application. In particular, the examiner should take into consideration other amendments that may be necessary to the claims, for example, to overcome any negative statement with regard to novelty, inventive step (non-obviousness) and/or industrial applicability. Observations with regard to issues of clarity and support therefore need not be included when it is highly likely that amendments will have to be made in order to overcome other objections and these amendments would also resolve the clarity and support issues. On the other hand, where an opinion or a report includes a positive statement with regard to novelty, inventive step (non-obviousness) and industrial applicability in respect of all claims, the opinion or report should raise any significant and pertinent matters concerning clarity and support. (See also paragraphs 5.31 to 5.58 and 17.09).

Finalization of the Report

Rules 70.3, 70.4, 70.14; Section 612

47.4717.51 When finalizing the international preliminary examination report, the Authority indicates the date on which the demand for international preliminary examination was submitted, the date on which the report was completed and the name and address of the International Preliminary Examining Authority. These last-mentioned items may either be completed when including the other data or when completing the report. Every written opinion and international preliminary examination report indicates the name of an authorized officer and of the International Authority responsible for that opinion or report.

Language of the Written Opinion and the International Preliminary Examination Report

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

47.4817.52 The written opinion and the international preliminary examination report, together with its annexes, if any, are established in the language of publication, or, if the international search and/or the international preliminary examination is carried out on the basis of a translation of the international application, in the language of that translation. An international application filed in Arabic, Chinese, English, French, German, Korean, Japanese, Portuguese, Russian or Spanish is published in that language; an international application filed in any other language is published in the language of a translation into one of these languages.

Form of Objection

Rule 66.2(b)

<u>47.4917.53</u> For each ground of objection, the first written opinion (in general, this will be the written opinion of the International Searching Authority) should indicate the part of the international application which is deficient and the requirement of the PCT which is not met either by referring to specific Articles or Rules, or by other clear explanation; it should also give the reason for any objection.

47.5017.54 If the cited art is such as to demonstrate lack of novelty or inventive step in the main claim or claims, and if consequently there is lack of unity of invention between dependent claims, if there is enough time, the applicant may be notified of this situation by the International Searching Authority and invited to pay additional search fees (see also paragraphs 10.60 *et seq*) prior to the international search report and the first written opinion being established. Subsequently, if a demand for international preliminary examination is filed and if, in the opinion of the International Preliminary Examining Authority, any response of the applicant (see paragraph 19.26) does not overcome the objection of lack of unity of invention, the Authority thereafter adopts the procedure described in paragraphs 10.74 to 10.82.

Ensuring Report Is of Maximal Use for Later Stages

47.51_17.55 Substantive matter in the written opinion should normally be set out first. The opinion should be drafted in such a manner as to facilitate further international preliminary examination of the international application should it be amended, and, in particular, to avoid the need for extensive re-reading should the examiner wish to issue one or more additional written opinions during the international preliminary examination (see paragraphs 19.26 to 19.29). Although the examiner is not obliged to do so, he should try to indicate to the applicant those amendments which would avoid a negative statement in the international preliminary examination report if a demand for international preliminary examination is filed. In the case of the written opinion of the International Searching Authority, the report should be set out so that it will be easily used by designated Offices in the event that its content is published as an "international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)" (see paragraph 2.18).

Invitation to Correct or Amend

Rules 43bis.1(c)

17.5217.56 The written opinion of the International Searching Authority includes a notification to the applicant that in the event that he demands international preliminary examination he is invited to file with the International Preliminary Examining Authority his observations, to correct any formal deficiencies and otherwise to submit amendments to the description, claims and drawings before the expiration of the time limit within which he may file his demand (see paragraph 22.14).

Rules 66.2(c), and (d)

47.5317.57 Any written opinion established by the International Preliminary Examining Authority must fix the time limit within which the applicant must reply. The time limit must be reasonable under the circumstances. It is normally two months after the date of the written opinion. In no case may it be shorter than one month after the said date. It must be at least two months after the date when the international search report was transmitted along with the written opinion of the International Searching Authority. In no case should it be more than three months after the date of the written opinion.

47.54_17.58 __Where a demand for Chapter II is filed, failure to reply to the invitation, whether from the written opinion of the International Searching Authority or from a written opinion actually established by the International Preliminary Examining Authority, may cause the international preliminary examination report to be established with a negative determination in relation to certain claims.

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

- | 17.5517.59 The statement in paragraph 17.09, that the written opinion should cover all the relevant issues, only sets out the general rule. There may be cases when either the Authority is not required to perform an international preliminary examination covering the whole of the international application, or else that it is more efficient to defer some matters until later. These may include:
 - (i) only inventions which have been searched need be the subject of international preliminary examination (Rule 66.1(e)) and consequently included within the written opinion;
 - (ii) cases where the international application relates to subject matter on which the International Preliminary Examining Authority is not required to carry out an international preliminary examination;
 - (iii) cases where the claims lack unity of invention;
 - (iv) situations in which a fundamental objection arises, for example, it is clear that certain claims lack novelty and that the claims will have to be drastically recast; or
 - (v) where the written opinion is established by the International Preliminary Examining Authority, the applicant may have submitted substantial amendments which add subject matter which goes beyond the disclosure of the international application as originally filed.

Excluded Subject Matter

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

47.5617.60 In the event that the examiner finds that the international application contains subject matter falling within Article 34(4)(a)(i) (that is, subject matter on which the International Authority is not required, under Rule 67 and Rule 43*bis*.1(b), to carry out examination) or that all the claims of the international application lack compliance with Article 34(4)(a)(ii) (that is, the description, the claims or the drawings are so unclear, or the claims are so inadequately supported by the description that no meaningful opinion can be formed), he indicates this defect or these defects in his first written opinion and does not go into the question, in that opinion, of whether the claimed invention appears to be novel, appears to involve an inventive step and is industrially applicable. (As discussed in Chapter 9, these instances should be rare.) Where any such defect affects only some of the claims, a similar approach is adopted in respect of such claims. These grounds for limiting the scope of the opinion are considered in detail in paragraph 9.17. It should be emphasized that, although the first written opinion is drawn up by the International Searching Authority, according to Rule 43*bis*.1(b), the conditions which are considered for this purpose are those which would apply to the International Preliminary Examining Authority.

Lack of Unity of Invention

- Written Opinion of the International Searching Authority
- 17.5717.61 The written opinion of the International Searching Authority should be established for those inventions for which the international search report is established.
- - Written Opinion of the International Preliminary Examining Authority or the International Preliminary Examination Report
- | 17.5917.63 Where the International Searching Authority has already issued an invitation to pay additional international search fees, or where the International Searching Authority could

have issued an invitation to pay additional search fees but chose not to, it may be appropriate for the International Preliminary Examining Authority to issue an "Invitation to Restrict or Pay Additional Fees" (Form PCT/IPEA/405).

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

47.6017.64 If the applicant does not comply with the invitation (by not paying the additional fees or by not restricting the claims either sufficiently or at all), the written opinion of the International Preliminary Examining Authority or international preliminary examination report is established on those parts of the international application which relate to what appears to be the first claimed invention (main invention) and the examiner indicates the relevant facts in such report.

17.61 The issues and processes concerning unity of invention, including payment of additional fees under protest, are covered in more detail in Chapter 10.

Dealing with Major Objections First

| 17.62 | 17.66 | In the event that fundamental objections arise, including ones which have been introduced by amendment (only applicable to international preliminary examination), it may be more appropriate to deal with this these objections before making a detailed examination; if, for example, the claims need re-casting, it may be pointless to raise objections to the clarity of some dependent claims or to a passage in the description which may have to be amended or even deleted as a consequence. However, if there are other major objections, these should be dealt with. The examiner should, at the first written opinion stage, seek to make the maximum impact with the broad aim of providing a useful international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty) if the applicant does not demand international preliminary examination and bringing proceedings to a conclusion without any undue delay in order to meet the relevant time limits if international preliminary examination is demanded (see paragraphs 19.07 to 19.10).

Other Considerations

Citation of Certain Documents in the International Search Report

47.6317.67 The international search report may cite a document which is not in a working language of the International Searching Authority because the search examiner knows or has strong evidence leading him to suspect (for example, from the drawings, from an abstract, a corresponding patent in a known language, or from a translation produced by some other person familiar with the language of the document) that the document is relevant. Where the intent is to provide more than one written opinion, in that circumstance, the examiner, in his first written opinion, may cite the document on the basis of similar evidence; an abstract or corresponding document in a working language of the International Preliminary Examining Authority, if known to the examiner, will also be cited. If, however, the applicant's response to the first written opinion disputes the relevance of the document and gives specific reasons, the examiner should consider whether, in the light of these reasons and of the other prior art available to him, he is justified in pursuing the matter. If so, he may obtain a translation of the document (or merely the relevant part of it if that can be easily identified). If he remains of the view that the document is relevant, he should consider whether it is necessary to send a copy of the translation to the applicant either with an additional written opinion or by way of an informal communication with the applicant.

Additional Documents Taken Into Consideration in Certain Cases

Article 33(6)

<u>47.64_17.68</u> Although, in principle, international preliminary examination is based on the international search report <u>(and any supplementary international search report available to the International Preliminary Examining Authority)</u>, the examiner should not be deterred from looking for relevant documents which he personally knows, or has reason to suspect, exist, if he can locate such documents in a short time from material available to him. Such

documents are considered on the same footing as the documents cited in the international search report.

47.6517.69 If the International Bureau transmits a third party observation to the International Preliminary Examining Authority in time to be taken into account in drawing up the international preliminary examination report, any prior art referred to in the observation should be considered in the same way as if it had been referred to in the international search report, provided that either a copy of the prior art is included or it is otherwise immediately available to the examiner. The examiner is not required to comment on a document referred to in a third party observation unless he considers it appropriate to cite it. The examiner may, if considered useful, state in Box No. V that third party observations submitted on specified dates have been taken into account in preparing the opinion on novelty and inventive step.

Inconsistencies Between Description and Claims

47.6617.70 While any serious inconsistencies between the claims and description as filed should be objected to (see paragraphs 5.29 and 5.30), it should be borne in mind that the claims may also require substantial amendment. In such a situation during the international preliminary examination procedure, the examiner might invite the applicant to amend the description to be in conformity with the final form of the amended claims even though the final form of the main claims may still not be settled. This procedure may help the examiner to expedite the issuance of the international preliminary examination report if a demand for international preliminary examination is filed. However, it should also be appreciated that the applicant should not be put to unnecessary expense and trouble in providing an amended description if there is any likelihood that the claims will have to be changed again.

Recommending Amendments

47.6717.71 The examiner should not suggest amendments merely because he thinks they will improve the wording of the description or claims. A pedantic approach is undesirable; what is important is that the meaning of the description and the claims should be clear. Although the examiner is not obliged to do so, he should try to indicate to the applicant those amendments which would avoid a negative statement in the international preliminary examination report if a demand for international preliminary examination is filed. It must be emphasized that it is not part of the duty of the examiner to invite the applicant to amend the international application in a particular way to meet an objection, since the drafting of the application is the applicant's responsibility and he should be free to amend in any way he chooses provided that the amendment removes the deficiency and otherwise satisfies the requirements of the PCT. However, it may sometimes be useful if the examiner suggests, at least in general terms, an acceptable form of amendment; but if he does so, he should make it clear that the suggestion is merely for the assistance of the applicant and that other forms of amendment will be considered. The form of the amendment should be as prescribed in Rule 66.8(a).

Consideration of Responses to the Written Opinion

<u>17.69</u>17.73 If the applicant submits arguments in response to the written opinion, the examiner should comment on the applicant's relevant arguments in the written opinion of the

International Preliminary Examining Authority and/or the international preliminary examination report.

PART VI THE INTERNATIONAL PRELIMINARY EXAMINATION STAGE (OTHER THAN THE INTERNATIONAL PRELIMINARY REPORT)

Chapter 18 Preliminary Procedure on Receipt of the Demand

Use of Facsimile Machine, Telegraph, Teleprinter, Etc.

Rule 92.1(a), 92.4(d), (g), and (h)

18.01 The International Preliminary Examining Authority may agree to receive a document by facsimile machine, telegraph, teleprinter or other like means of communication resulting in the filing of a printed or written document. If required under Rule 92.4(d), it checks whether the original document is timely furnished in a form complying with the requirements of Rule 92.1(a) within 14 days after the document was transmitted. If the original document is timely received, or not required, the International Preliminary Examining Authority considers that the document was validly submitted on the date on which it was received by the means mentioned above. If a document is considered not to have been submitted, the International Preliminary Examining Authority notifies the applicant accordingly (Form PCT/IPEA/423).

Basis for International Preliminary Examination

18.02 Box No. IV of the demand Form is divided into two parts. The first part provides for the statement concerning amendments. The second part provides for the indication of the language for the purposes of international preliminary examination. Details on both parts are given in the following paragraphs.

Statement Concerning Amendments

Rules 53.9, 60.1(f)

18.03 The first part of Box No. IV of the demand Form provides check boxes for the applicant to indicate the basis on which international preliminary examination should start. Where none of the boxes are marked or where the applicant has indicated that the international preliminary examination is to start on the basis of the international application as originally filed, the file is forwarded to the examiner as soon as all formal (including any required translation of the international application and/or of amendments, see paragraphs 22.12 to 22.14) and fee matters are resolved.

Article 34; Rules 60.1(g), 69.1(e); Section 602(a)(i) to (iii)_and (b) 18.04 Where the international preliminary examination is to take into account amendments under Article 34, but the applicant failed to submit them with the demand, the International Preliminary Examining Authority invites the applicant (Form PCT/IPEA/431) within a reasonable time limit fixed in the invitation to submit the amendments. Whether the

amendments are submitted with the demand or subsequently, they are marked in accordance with Section 602(a)(i) to (iii) and (b) of the Administrative Instructions before the file is then-forwarded to the examiner.

Article 19; Rule 62.1; Section 602

18.05 Where the applicant has marked the appropriate check box in Box No. IV of the demand that amendments under Article 19 and any accompanying statement are to be taken into account, the International Preliminary Examining Authority indicates on the last sheet of the demand whether a copy of such amendments and any accompanying statement was actually submitted with the demand. Where no copy of the amendments under Article 19 was submitted with the demand, examination does not start until a copy of such amendment and any accompanying statement are received from the International Bureau. After the International Bureau receives the demand, it promptly transmits to the International Preliminary Examining Authority the copy of the amendments under Article 19 and any

accompanying statement submitted as well as the letter required under Rule 46.5(b). The International Preliminary Examining Authority marks the copy of the amendments submitted with the demand or received later, in accordance with Section 602(a)(i) to (iii) and (b) of the Administrative Instructions before the file is forwarded to the examiner. If no amendments under Article 19 have been made at the time when the demand is received by the International Bureau, the International Preliminary Examining Authority is so informed by the International Bureau. However, any International Preliminary Examining Authority can waive the sending by mail of the information that no Article 19 amendments were received by the International Bureau (Form PCT/IB/337), but instead may opt to receive such information in electronic form.

Article 19; Rules 46.1, 53.9(b), 69.1(d)

18.06 If the same national Office or intergovernmental organization which acts as International Searching Authority is also to act as International Preliminary Examining Authority and wishes to start the international preliminary examination at the same time as the international search in accordance with Rule 69.1(b), but the demand includes a statement that the start of the international preliminary examination is to be postponed under Rule 53.9(b) because the time limit for filing amendments under Article 19, as provided in Rule 46.1, has not expired, the International Preliminary Examining Authority waits until it receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make amendments under Article 19 before beginning the international preliminary examination. Where neither a copy of the amendments nor a notice has reached the International Preliminary Examining Authority by the expiration of 22-16 months from the priority date or three-two months from the date of transmittal of the international search report, whichever expires later (the time limit in accordance with Rule 46.1 for filing amendments under Article 19), examination starts on the basis of the documents in the file.

Language for the Purposes of International Preliminary Examination

Rule 55.2

18.07 The second part of Box No. IV of the demand Form provides for the indication (on the dotted line) of the language in which international preliminary examination is to be carried out; it also provides check boxes to be marked depending on what that language is. That language will be:

Rule 55.2(a)

(i) the language in which the international application was filed (that will be the case in most instances);

Rule 55.2(b)

(ii) the language of a translation furnished for the purposes of the international search (in a case where the language in which the international application was filed is not a language in which the international search is to be carried out);

Rules 48.3(b), 55.2(b)

(iii) the language in which the international application was published (in a case where the language in which the international application was filed and the language in which the international search was carried out is are not a languages of publication; or

Rule 55.2(a), and (a-bis), (b)

(iv) _____the language of a translation furnished for the purposes of international preliminary examination, provided that that language is a language accepted by the Authority and a language of publication (in a case where neither the language of a translation furnished for the purposes of international search nor the language of publication are languages accepted for the purposes of international preliminary examination). This translation must include any element referred to in Article 11(1)(iii)(d) or (e) furnished by the applicant under Rule 20.3(b) or 20.6(a) and any part of the description, claims or drawings furnished by the applicant under Rule 20.5(b) or 20.6(a) which is considered to have been contained in the international application under Rule 20.6(b).

18.08 Where none of the check boxes is marked, the file is forwarded to the examiner as soon as it is determined what is the language in which international preliminary examination will be carried out (and when any required translation of the international application and/or of amendment) has been furnished) and when all other formal and fee matters are resolved.

Rule 55.2(c), 55.3(bc)(d)

18.09 Where the international preliminary examination is to be carried out on the basis of a translation of the international application and/or of amendments, but the applicant failed to submit them with the demand (including translations of any late filed missing elements or parts of the application - see paragraph 18.07(iv)), the International Preliminary Examining Authority invites the applicant (Form PCT/IPEA/443) to submit the missing items within a reasonable time limit fixed in the invitation. The same applies where a letter required under Rule 66.8(a) or Rule 46.5(b) is not provided in the language of the translation of the application. Whether the sheets containing the translation and/or amendments are submitted with the demand or subsequently, they are marked in accordance with Section 602(a)(i) to (iii) and (b) of the Administrative Instructions before the file is then forwarded to the examiner. Furthermore, where a translation filed according to Rule 55.2(a) does not comply with the physical requirements of Rule 11 to an extent necessary for the purposes of international preliminary examination, the International Preliminary Examining Authority will also invite the applicant to provide a correction of that translation. If the applicant fails to comply with an invitation to furnish a translation of an amendment, the amendment shall not be taken into account during international preliminary examination. If the applicant fails to comply with an invitation to furnish an accompanying letter, the amendment need not be taken into account during international preliminary examination.

Documents, Etc., for the International Preliminary Examining Authority

- 18.10 The examiner will, where the International Preliminary Examining Authority is part of the same national Office, or intergovernmental organization as the International Searching Authority, have in the file in addition to the demand (see paragraph 19.07), description, drawings (if any), the claims, as originally filed and the abstract as originally filed or established by the International Searching Authority, or, where necessary, their translation (see paragraph 18.11); any amendments proposed to date; a notification that no amendments have been filed or will be filed under Article 19, unless waived by the Authority; the international search report with the applicant's comments (if any), and copies of any cited documents; the written opinion of the International Searching Authority; and, depending on the circumstances, the request and correspondence concerning formalities from the receiving Office, the International Searching Authority or the International Bureau, the priority document as well as any required translations (see paragraphs 6.17 and 18.07).
- 18.11 Where a translation of the international application is required under Rule 55.2 and the International Searching Authority and the International Preliminary Examining Authority are part of the same national Office or intergovernmental organization, the international preliminary examination is carried out on the basis of any translation transmitted to the International Searching Authority under Rule 23.1(b) unless the applicant furnishes a further translation for the purposes of the international preliminary examination.
- 18.12 In the cases where the international search has been performed by an International Searching Authority which is not part of the same national Office or intergovernmental organization as the International Preliminary Examining Authority, the various elements of the file making up the international application will be supplied to the International Preliminary Examining Authority as follows:

Article 31(6)(a)

- (i) the demand: by the applicant:
- (ii) the request, description, drawings (if any), claims, and sequence listing filed under the provisions of Section 801 (if applicable), as originally filed: by the International Bureau:

Rule 43bis

(iii) the international search report <u>or the declaration under Article 17(2)(a)</u>, and <u>the written opinion or declaration under Article 17(2)(a) established under Rule 43*bis*.1: by the International Bureau;</u>

Rule 55.2

(iv) where neither the language in which the international application is filed nor the language in which the international application is published is accepted by the International Preliminary Examining Authority, a translation of the international application into a language which is both a language accepted by the International Preliminary Examining Authority and a language of publication: by the applicant (see, however, paragraph 18.11);

Rule 62

(v) amendments and statement under Article 19 (if any): where the applicant has marked the appropriate check box in Box No. IV of the demand (Form PCT/IPEA/401) that amendments under Article 19 are to be taken into account, the International Preliminary Examining Authority indicates on the last sheet of the demand whether a copy of such amendments was actually received with the demand. Where no copy of the amendments under Article 19 was received with the demand, a copy of such amendment will be transmitted by the International Bureau promptly after that Bureau receives the demand. If no amendments under Article 19 have been made at the time when the demand is received by the International Bureau, the International Preliminary Examining Authority is so informed by the International Bureau. If, at the time of filing such amendments, the demand has already been submitted, the applicant should also submit a copy of such amendments to the International Preliminary Examining Authority. In any event, the International Bureau will promptly transmit a copy of any amendments under Article 19 to the International Preliminary Examining Authority;

Rule 13ter.1; Section 208; Al Annex C

(vi) nucleotide and/or amino acid sequence listing in written form and/or in computer readablepaper and/or electronic form, both forms complying with the standard provided for in Annex C of the Administrative Instructions: where the International Searching Authority and the International Preliminary Examining Authority are part of the same national Office or intergovernmental organization, by the International Searching Authority; otherwise, by the applicant;

Rule 66.1

- (vii) amendments according to Article 34(2)(b): by the applicant;
- (viii) copies of any documents cited in the international search report which are not available from the databases of the International Preliminary Examining Authority: by the International Searching Authority;

Rule 66.7(a)

(ix) priority document: by the International Bureau;

Rule 66.7(b)

- (x) translation of the priority document where required: by the applicant (subject to an invitation to furnish the translation having been made, see paragraph 18.16).
- 18.13 The examiner should keep in mind that the documents making up the international application may contain, instead of an international search report, a the declaration referred to inaccording to Article 17(2)(a) instead of an international search report, and written opinion of the International Searching Authority, that is, the a declaration of by the International Searching Authority that it considers that the international application relates to a subject matter which it was not required to search and decided not to search, or that the description, the claims, or the drawings failed to comply with the prescribed requirements to such an extent that a meaningful search could not be carried out. In this case, the examiner should appraise the declaration as if it were the international search report.

Language of the International Application and of the Demand

Rule 55

- 18.14 The demand submitted to the International Preliminary Examining Authority must be in the language of the international application or, if the international application has been filed in a language other than the language in which it is published, in the language of publication or, if a translation of the international application is required under Rule 55.2, in the language of that translation. If the demand is not submitted in this language, the Authority invites the applicant to correct the defect (Form PCT/IPEA/404, see paragraph 22.24). If the applicant does not timely comply with the invitation, the International Preliminary Examining Authority considers the demand as having not been submitted and issues a declaration to that effect by sending a copy of Form PCT/IPEA/407 to the applicant and the International Bureau.
- 18.15 If the international preliminary examination is carried out on a translation of the original application into a language of publication, or on a translation under Rule 55.2, it may be difficult to determine whether any amendments filed under Article 34(2)(b) extend the content of the international application as filed. See paragraph 20.11 for procedure in such a case.

Priority Document and Translation Thereof

Rule 66.7(a), and (b)

18.16 Where the international application claims the priority of a previous application and the examiner needs the priority document, the examiner should request the International Bureau to furnish promptly a copy of the priority document. When the priority document is not in the language or in one of the languages of the International Preliminary Examining Authority, the examiner may invite the applicant to furnish a translation of the priority document (see paragraph 6.17). If the examiner finds that the requested priority document or (where required) the translation have not been timely furnished, he may establish the international preliminary examination report as if the priority has not been claimed in the international application and indicate this in the report.

Nucleotide and/or Amino Acid Sequence Listings

Rule 13ter.1(a), (c) and (e); Section 208; Al Part 8; Al Annex C

18.17 Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences and a corresponding sequence listing in written paper (or image file) form and in computer readable electronic form for the purposes of international preliminary examination (both forms complying with the standard provided for in Annex C of the Administrative Instructions) the International Preliminary Examining Authority carries out the international preliminary examination on the basis of those listings. Instead of a written form, the sequence listing may be provided on an electronic medium under the provisions of Section 801 of the Administrative Instructions (see paragraph 4.15).

Rule 13ter.1(a), (c) and (e), 13ter.2, Section 208; Al Annex C

18.18 Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences but does not contain a corresponding sequence listing in written-paper (or pdfimage file) form and/or in computer readable electronic form complying with the standard provided for in Annex C of the Administrative Instructions, the International Preliminary Examining Authority may invite the applicant (with Form PCT/IPEA/441) to furnish to it, within a time limit fixed in the invitation, a sequence listing in written-paper (or pdfimage file) form and/or computer readable electronic form, as the case may be, complying with the standard. The furnishing of a sequence listing in response to an invitation by the International Preliminary Examining Authority may be subject to the payment of a fee set by the International Preliminary Examining Authority, which may not exceed 25% of the international filing fee (not taking into account any fee for each sheet of the international application in excess of 30 sheets). If the applicant complies with the invitation, the procedure outlined in the preceding paragraph applies. If the applicant does not comply with

the invitation within the time limit or the response to the invitation is defective, the International Preliminary Examining Authority is not-required to carry out the international preliminary examination only to the extent that such non-compliance has the result that a meaningful examination cannot can be carried out without the sequence listing (see paragraph 9.39).

Chapter 19

Examination Procedure Before The International Preliminary Examining Authority

General

19.01 The present chapter sets out the procedure before the International Preliminary Examining Authority with respect to international preliminary examination from the time such examination starts.

Article 33(1), (2), (3), and (4)

- 19.02 The objective of international preliminary examination of an international application is to formulate a preliminary and non-binding opinion as to:
 - (i) whether the claimed invention appears to be "novel" (see Chapter 12);
- (ii) whether the claimed invention appears to involve an "inventive step" (is non-obvious) (see Chapter 13); and
- (iii) whether the claimed invention appears to be "industrially applicable" (see Chapter 14).

Article 33(5); Rule 5.1(a)(iii)

- 19.03 Although these criteria serve as the basis for international preliminary examination, any Contracting State may apply additional or different criteria for the purposes of deciding whether or not, in that State, the claimed invention will be protected (that is, by a patent, an inventor's certificate, a utility certificate or a utility model).
- 19.04 In addition to these basic three criteria, the examiner should be aware of the following two criteria that are implicitly contained in the Treaty and the Regulations:
- (i) the invention must be such that it can be carried out by a person skilled in the art (after proper instruction by the application); this follows from Article 5. See paragraphs 5.43 *et seg*;
- (ii) the invention must relate to a technical field (Rule 5.1(a)(i)), must be concerned with a technical problem (Rule 5.1(a)(iii)) and must have technical features in terms of which the subject matter for which protection is sought can be defined in the claim (Rule 6.3(a)) (see paragraph 5.04). The PCT does not require that a claimed invention be an advance over the prior art. However, advantageous effects, if any, may be relevant to determining "inventive step" (see Chapter 13).

Articles 34(2)(c), 35

19.05 The results of the international preliminary examination, in the course of which one or more written opinions may be issued to the applicant by the International Preliminary Examining Authority and other communications with the applicant may occur, are given in an international preliminary examination report established by that Authority.

Start of, and Time Limit for, International Preliminary Examination

Article 31(2), (3), and (4)

19.06 Prior to the start of international preliminary examination of an international application, the applicant must, of course, have filed a demand (Form PCT/IPEA/401) that his international application be made the subject of an international preliminary examination. Chapter 18 gives details of the actions which take place on receipt of the demand before the examiner begins the international preliminary examination itself.

Start of Examination

Rule 69.1

19.07 The International Preliminary Examining Authority starts the international preliminary examination when it is in possession of the demand; if the applicant is required to furnish a translation under Rule 55.2, that translation; and of either the international search report and the written opinion established under Rule 43*bis*.1 or a notice of the

declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established, provided that the International Preliminary Examining Authority does not start the international preliminary examination before the expiration of the later of three months from the transmittal of the international search report and written opinion or of the declaration that no international search report will be established; or the expiration of 22 months from the priority date unless the applicant expressly requests an earlier start, with the exception of the following situations:

- (a) If the competent International Preliminary Examining Authority is part of the same national Office or intergovernmental organization as the competent International Searching Authority, the international preliminary examination may, if the International Preliminary Examining Authority so wishes, start at the same time as the international search, provided that the examination is not to be postponed according to the statement concerning amendments.
- (b) Where the statement concerning amendments contains an indication that amendments under Article 19 are to be taken into account (Rule 53.9(a)(i)), the International Preliminary Examining Authority does not start the international preliminary examination before it has received a copy of the amendments concerned. These will be transmitted to the International Preliminary Examining Authority by the International Bureau. If a demand for international preliminary examination has already been submitted, the applicant should preferably, at the time he files the Article 19 amendments with the International Bureau, also file a copy of the amendments with the International Preliminary Examining Authority.
- (c) Where the statement concerning amendments contains an indication that the start of the international preliminary examination is to be postponed (Rule 53.9(b)), the International Preliminary Examining Authority does not start the international preliminary examination before:
- (i) it has received a copy of any amendments made under Article 19;
- (ii) it has received a notice from the applicant that he does not wish to make amendments under Article 19; or
- (iii) the later of three months from the transmittal of the international search report and written opinion or of the declaration that no international search report will be established; or the expiration of 22 months from the priority date;

whichever occurs first.

(d) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority does not start the international preliminary examination before it has received the amendments or before the time limit fixed in the invitation referred to in Rule 60.1(g) has expired, whichever occurs first.

Rul<u>e 69.1</u>

- 19.07 <u>The International Preliminary Examining Authority normally starts the international preliminary examination (see Chapter 19)</u> when:
 - (a) it is in possession of:
 - (i) the demand;
- (ii) the amount due (in full) for the handling fee and the preliminary examination fee, including, where applicable, the late payment fee under Rule 58bis.2;
- (iii) if the applicant is required to furnish a translation under Rule 55.2, that translation; and

(iv) either the international search report or the declaration by the International Searching Authority under Article 17(2)(a) that no international search report will be established, and the written opinion established under Rule 43bis.1;

and

- (b) the time limit within which the applicant was permitted to file the demand (see paragraph 3.07) has expired, or earlier if the applicant has expressly requested an earlier start.
- 19.08 The exceptions to the above are as follows:

Rule 69.1(c)

(a) Where the statement concerning amendments contains an indication that amendments under Article 19 are to be taken into account (Rule 53.9(a)(i)), the International Preliminary Examining Authority does not start the international preliminary examination until it receives a copy of the amendments concerned.

Rule 69.1(e)

(b) Where the statement concerning amendments contains an indication that amendments under Article 34 are submitted with the demand (Rule 53.9(c)) but no such amendments are, in fact, submitted, the International Preliminary Examining Authority does not start the international preliminary examination until it receives the amendments or the time limit fixed in the invitation referred to in Rule 60.1(g) expires (see paragraph 18.04), whichever occurs first.

Rule 69.1(b) and (d)

(c) If the national Office or intergovernmental organization that acts as International Searching Authority also acts as International Preliminary Examining Authority, the international preliminary examination may, if that Office or organization so wishes, start at the same time as the international search (subject to the possible need to invite the applicant to provide copies of amendments under Article 34, as noted in paragraph (b), above), provided that the applicant has not indicated (under Rule 53.9(b)) in the statement of amendments that examination is to be postponed until after the expiry of the time limit for filling amendments under Article 19 (such amendments only being permitted after the international search report has been received). Where the statement concerning amendments contains such an indication, the International Preliminary Examining Authority does not start the international preliminary examination until it receives a copy of any amendments made under Article 19, or a subsequent notice from the applicant that he does not wish to make amendments under Article 19, or the time limit under Rule 46.1 for filing Article 19 amendments expires, whichever occurs first.

Rule 45bis.8(c), (d)

19.09 Any supplementary international search reports which are transmitted to the Authority in sufficient time should be taken into account for the purpose of a written opinion or international preliminary examination report as if they were a part of the main international search report. On the other hand, supplementary international search reports do not need to be taken into account if they are received by the Authority after it has started to draw up an opinion or report.

Time Limit for Completing Examination

Rule 69.2

- 19.0919.10 The time limit for the establishment of the international preliminary examination report is the same for all International Preliminary Examining Authorities and is set out in Rule 69.2. This time limit may not exceed whichever expires last of:
 - (i) 28 months from the priority date;
 - (ii) six months from the time period provided under Rule 69.1 for the start of the international preliminary examination; or

- (iii) six months from the date of receipt by the International Preliminary Examining Authority of the translation furnished under Rule 55.2.
- 49.10_19.11 If, in case of lack of unity of invention, the time limit cannot be met, the international preliminary examination report must be established promptly after the receipt of additional preliminary examination fees or after the expiration of the time limit for payment of such fees, if no such payment is made.

Rule 69.1(b)_and (b-bis) 19.11_19.12 Where the International Preliminary Examining Authority is part of the same national Office or intergovernmental organization as the International Searching Authority, the international search and the international preliminary examination may start at the same time. In such a situation, if the application does not comply with Article 34(2)(c), the International Searching Authority will issue a written opinion. Any further written opinions will be issued by the International Preliminary Examining Authority. However, if a positive international preliminary examination report can be issued, the International Preliminary Examining Authority may establish the international preliminary examination report directly without the issuance of a written opinion by the International Searching Authority. See paragraph 19.22.

First Stage of International Preliminary Examination

General

- 19.12 The examiner should consider if unity of invention exists. If the examiner finds that lack of unity exists, he may issue an invitation to restrict the claims to a single searched invention or subject to Rule 66.1(e) pay additional fees to examine additional inventions before carrying out a top-up search or the issuance of either a written opinion at the international preliminary examination stage or the international preliminary examination report. See Chapter 10 for further details.
- 19.13_19.14 The international preliminary examination is carried out in accordance with Article 34 and Rule 66. A written opinion will normally have been established on the application by the International Searching Authority. Usually this is considered as the first written opinion of the International Preliminary Examining Authority (see paragraph 3.19 for the exceptions to this). The examiner performing the international preliminary examination, if he has not already done so during the international search, studies the description, the drawings (if any), and the claims of the international application, including any amendments and observations which may have been filed, and the documents describing the prior art as cited in the international search report, as well as any documents cited in a supplementary international search report and/or submitted by third parties. The examiner then carries out a top-up search in accordance with Rule 66.1 ter unless he considers that such a search would serve no useful purpose. He then determines whether a further written opinion (or a first written opinion in the exceptional case where a written opinion of the International Searching Authority has either not been prepared or else is not treated as the first written opinion of the International Preliminary Examining Authority) is required.

Rule 66.1ter

- 19.14_19.15 In general, the examiner should carry out a top-up search during the international preliminary examination process. However, when he considers that a top-up search would serve no useful purpose, he need not carry out such a search. This is the case, for example, when it is decided that the international application, in its entirety, relates to subject matter on which the International Preliminary Examining Authority is not required to carry out an international preliminary examination, or that the international application is so unclear or the claims are so inadequately supported by the description that no meaningful opinion can be formed on the novelty, inventive step, or industrial applicability, of the claimed invention (see paragraphs 17.33 to 0). The same applies when no international search report has been established for certain claims and it is thus decided not to carry out an international preliminary examination on these claims (see paragraph 17.36). Note, however, that when any of the above situations applies to only part of the claimed subject matter or where there is lack of unity of invention, a top-up search should still be carried out but may be restricted to those parts of the international application that are the subject of international preliminary examination.
- 49.15_19.16 In the case of non-unity where there is more than one invention claimed in the application for which international preliminary examination is demanded, the examiner may first issue an invitation to restrict the claims or pay additional examination fees and then perform the top-up search for all inventions for which preliminary examination fees have been paid, provided that any such inventions are not excluded from international preliminary examination by the examiner under Rule 66.1(e).
- 49.1619.17 As a general rule, a top-up search will be conducted for all the claims that are the subject of international preliminary examination. In the special case that the application is amended but the basis for the amendments could not be found, and/or there is no letter explaining the basis, and the examiner decides under Rule 70.2(c) or Rule 70.2(c-bis) to establish the report as if the amendments had not been made, the top-up search may be limited to the scope of the claims forming the basis for the report.
- | 19.1719.18 A_top-up search is normally carried out at the start of the international preliminary examination. In certain cases, it may be delayed to a later stage before the establishment of the international preliminary examination report.

Rule 66.1ter

- 19.18_19.19 The main objective of the top-up search is to discover any relevant documents referred to in Rule 64 which have become available to the International Preliminary Examining Authority for search subsequent to the date on which the international search report was established. The top-up search is primarily directed towards the earlier filed but later published patent applications or patents within the meaning of Rule 64.3. However, it should also be directed to normal prior art (Rule 64.1) or evidence of non-written disclosures (Rule 64.2) with the aim of discovering any such documents which had not been available to the International Searching Authority due to certain circumstances such as a delay in collecting the documents into its database.
- <u>19.1919.20</u> The scope of the top-up search does not normally extend beyond that of the international search. However, the final determination as to the exact scope of the top-up search is left to the examiner.

Rules 66.1ter, 70.7, 70.10

paragraph 17.42), and any newly discovered documents as defined in Rule 64.2 and Rule 64.3 should be cited in Box. No. VI of the report (see paragraphs 17.46 and 17.47).

Cases Where No Written Opinion Is Required

Article 34(2)(c); Rule 69.1(b)

- 19.21_19.22 If the same Authority acts as both the International Searching Authority and the International Preliminary Examining Authority, and a demand has been filed before the written opinion of the International Searching Authority is prepared, no written opinion (see paragraphs 17.01 to 17.08) is required and the examiner may immediately establish the international preliminary examination report if:
- (i) the claimed invention satisfies the criteria specified in Article 33(1) (novelty, inventive step and industrial applicability);
- (ii) the application complies with the requirements of the PCT as regards the form and contents of the international application;
- (iii) the application meets the requirements on the clarity of the claims, the descriptions and the drawings and the claims are fully supported by the description as provided for in Article 35(2) and Rule 70.12(ii) or the examiner does not wish to make any observations thereon (Rule 66.2(a)(v));
- (iv) no amendment goes beyond the disclosure in the international application as filed;
- (v) all claims relate to an invention in respect of which an international search report is being established and an international preliminary examination report is being established in respect of all the claims; and
- (vi) if applicable, a nucleotide and/or amino acid sequence listing is available in such a form that a meaningful international preliminary examination can be carried out.

Furthermore, if the International Preliminary Examining Authority does not treat the written opinion of the International Searching Authority as a written opinion of the International Preliminary Examining Authority for the purposes of Rule 66.2(a), it similarly need not prepare a written opinion and may proceed directly to the international preliminary examination report provided that criteria (i) through (vi) above are satisfied.

| 19.2219.23 A further written opinion is not mandatory where the written opinion of the International Searching Authority is treated as the first written opinion of the International Preliminary Examining Authority. The examiner takes into consideration any comments or amendments made by the applicant when he establishes the international preliminary examination report.

Cases Where a Further Written Opinion May Be Issued

19.23_19.24 Assuming that the written opinion of the International Searching Authority is treated as the first written opinion of the International Preliminary Examining Authority, as noted above no further written opinion need be issued before the international preliminary examination report, even if there are objections outstanding. However, where the applicant has made a credible attempt to overcome or rebut the objections in the written opinion of the International Searching Authority, but failed to satisfy the examiner that all the relevant criteria are met, a further written opinion may, at the discretion of the International Preliminary Examining Authority, be issued if there is sufficient time available to establish the international preliminary examination report prior to expiration of the time period set in Rule 69.2 for establishment of the international preliminary examination report. Where the International Preliminary Examining Authority has carried out a top-up search and intends to raise objections based on prior art documents discovered in the top-up search, a further written opinion should be issued.

Claims for Which No International Search Report Has Been Established

Rule 66.1(e)

49.2419.25 It is to be noted that international preliminary examination can be carried out only on those inventions in respect of which the International Searching Authority has established the international search report. This follows from the requirement in Article 33(6) that the International Preliminary Examining Authority has to take into consideration the documents cited in the international search report (see, however, paragraph 10.73). Claims relating to inventions in respect of which no international search report has been established need not be the subject of international preliminary examination.

Further Stage of International Preliminary Examination

Article 34(2)(d); Rule 66.4(a), and (b) 19.2519.26 When the applicant has responded to a written opinion, the examiner may, if necessary and if sufficient time remains for the applicant to respond and for the international preliminary examination report to be established (see paragraphs 19.10 and 19.11), issue one or more additional written opinions. Likewise, if the applicant so requests, the examiner may give him one or more additional opportunities to submit amendments or arguments.

49.2619.27 The additional written opinion from the examiner should invite the applicant to submit a written reply together with, where appropriate, amendments. After receipt of this opinion, the applicant may respond by amending the claims, description and drawings or, if he disagrees with the opinion, submit arguments, as the case may be, or do both. The conditions for amendments set out in paragraphs 20.04 to 20.22 apply.

49.2719.28 The examiner should apply the same standard of international preliminary examination in relation to matters of substance at all stages in the processing of the international application. However, after the International Searching Authority has established a first written opinion, he will not normally need to completely re-read the amended application if he has drafted his first written opinion in a comprehensive way (see paragraph 17.55) but he should concentrate on the amendments themselves and any related passages, and on the deficiencies indicated in his first written opinion.

Rules 66.2, 66.4

49.2819.29 The examiner should be guided by the overriding principle that an international preliminary examination report should be established after as few written opinions as possible, and he should control the procedure with this always in mind. The PCT provides that the process of communicating with the applicant described in paragraph 19.30 may be repeated if the International Preliminary Examining Authority so wishes. Nevertheless, if it is clear that the applicant is not making any real effort to deal with the examiner's objections, either by amendments or by counter-arguments, then at the conclusion of the first, or second, written opinion stage the examiner should establish the international preliminary examination report (see paragraph 19.47). If the examiner has discovered any relevant documents in a top-up search and intends to raise new objections based on them, he should issue a second written opinion to notify the applicant accordingly. If the examiner determines that the issuance of an second additional written opinion would facilitate the final resolution of significant issues, the examiner should consider the issuance of such written opinion. The examiner may consider issuing an second additional written opinion, if there are still objections that are required to be met, provided that there is sufficient time available for the establishment of the international preliminary examination report within the time limit set in the treaty, that the applicant is making a real effort to meet the examiner's objection and that the International Preliminary Examining Authority has adequate resources (see paragraphs 19.26 and 20.05). The examiner may also consider whether outstanding issues would best be resolved by a further written opinion, a telephone discussion or an interview.

19.2919.30 If the matters are such that the applicant is likely to require time to consider them, the examiner may wish to issue an additional written opinion. If, however, there seems to be confusion about points in dispute, for example, if the applicant seems to have

misunderstood the examiner's reasons, or if the applicant's own argument is not clear, then it may expedite matters if the examiner proposes an interview. On the other hand, if the matters to be resolved are minor, or can quickly and easily be explained and dealt with, then they might be settled more expeditiously by telephone discussion. Discussion with the applicant by interview or telephone is more fully considered in paragraphs 19.41 to 19.46.

19.3019.31 Where a response to a written opinion is received in the form of arguments only, the written opinion is reconsidered in the light of those arguments. Where the response includes some amendments, other than rectification of obvious errors-mistakes (Rule 66.5), the amended description, drawings, and/or claims are considered as in paragraphs 20.04 to 20.22. In such a case the international preliminary examination report should indicate that the applicant's arguments have been taken in account in establishing the international preliminary examination report. In addition, the examiner should comment on any relevant arguments made by the applicant.

Rule 66.4bis

49.31_19.32 Where the time limit set for response to a further written opinion expires without a response being received, the file is forwarded to the examiner who prepared the opinion, who proceeds to establish the international preliminary examination report as in Chapter 17.

| 19.3219.33 | Where a response is received after the expiration of the time limit and the report has not yet been established, then the response can be considered. But note | Rule 66.4*bis* (amendments, or arguments or rectification of obvious mistakes need not be taken into account). See also paragraph 20.05.

Correction of International Preliminary Examination Report

Rule 66.4. 66.6

49.3319.34 The International Preliminary Examining Authority may establish a corrected international preliminary examination report in exceptional circumstances after a report has been issued, provided the circumstances justify such an action. Any replacement report resulting from the re-opening of international preliminary examination should be clearly labeled as such so that elected Offices are aware of its status. A corrected international preliminary examination report will not be established merely because the applicant disagrees with the international preliminary examination report established by the International Preliminary Examining Authority. The retraction of an international preliminary examination report should only be done under exceptional circumstances. The type of circumstance which justifies the re-opening of preliminary examination is where the report was issued earlier than it otherwise would have, by reason of an error or omission on the part of the International Preliminary Examining Authority. For example, the International Preliminary Examining Authority establishes the international preliminary examination report without consideration of a timely filed amendment. Note that once examination of a particular application has been re-opened, any subsequent request to re-open examination of that application should not be entertained.

49.34_19.35 __The International Bureau must be advised to disregard the earlier report. If the resulting response is a further written opinion, then this opinion will be sent to the applicant only. However when the resulting response is another international preliminary examination report, this will be sent to both the applicant and the International Bureau as a "corrected version" of the international preliminary examination report.

Matters Applicable Generally to Various Stages of International Preliminary Examination

Making Amendments: General Considerations

<u>19.3519.36</u> See chapter 20 for the factors which should be taken into account when considering amendments.

Rectification of Obvious Errors Mistakes

Rules 66.5, 91.1(b)

49.36_19.37 Errors Mistakes which are due to the fact that something other than that which was obviously intended was written in the contents of the international application (other than the request) or other paper submitted to the International Preliminary Examining Authority (for example, linguistic errors, spelling errors) may usually be rectified at any time during international preliminary examination be rectified if a request for rectification is submitted within 26 months from the priority date. If a correction is not of this character (for example, if it involves cancellation of claims, omission of passages in the description or omission of certain drawings), it would not be authorized by the Authority it is treated by the examiner as an amendment and dealt with on that basis (see paragraph 20.09 and Chapter 8).

Rule 91.1(d)

49.37_19.38 Subject to authorization (see paragraph 19.30), rectification of obvious errors mistakes in the international application can be made at the request of the applicant on his own volition. In addition, the examiner, upon study of the international application (other than the request) and any other papers submitted by the applicant, might also note obvious errorsmistakes. (See Chapter 8). Although Rule 91 allows the International Preliminary Examining Authority to invite the applicant to submit a request for rectifications, it is not foreseen that such invitations will be issued since any error which can be rectified under Rule 91 will not be an impediment to establishing the international preliminary examination report.

Rule 91.1(e), (f), and (g)(ii), 91.2; Section 607

19.39 Rectification of an obvious error cannot be made before the International Preliminary Examining Authority without the express authorization of that Authority. The Authority is permitted to authorize rectification of such errors-mistakes in a part of the international application other than the request or in any papers submitted to it. The Authority may only authorize rectification of obvious errors-mistakes if a request for rectification is submitted within 26 months from the priority date. up to the time the international preliminary examination report is established. See paragraph 8.14 to 8.17.

Rules 66.1(d-bis), 66.4bis

19.40 A rectification of an obvious mistake that is authorized under Rule 91.1 shall be taken into account by the International Preliminary Examining Authority for the purposes of the international preliminary examination. However, it need not be so taken into account for purposes of the written opinion or the international preliminary examination report if it is received by, authorized by, or notified to that Authority after it has begun to draw up that opinion or report.

Informal Communication with the Applicant

Rule 66.6

19.38_19.41 The International Preliminary Examining Authority may, at any time, communicate informally, over the telephone, in writing, or through personal interviews, with the applicant. The circumstances in which it may be appropriate for the examiner to communicate with the applicant by telephone or propose an interview rather than send an additional written opinion are considered in paragraphs 19.29 and 19.30. Communication will, in most instances, be with the applicant's agent (the meaning of "agent" in the PCT is set out in Rule 2.2) rather than the applicant himself. If the applicant, or his agent, requests an interview, the examiner, at his discretion, should grant more than one interview if he believes that a useful purpose would be served by such a discussion.

49.3919.42 When an interview is arranged, whether by telephone or in writing, and whether by the examiner or by the applicant, the matters for discussion should be stated. If the arrangement is made by telephone, the examiner should record the particulars and briefly indicate, on the file, the matters to be discussed.

Rule 66.6

49.40_19.43 The interview is an informal procedure and the recording of the interview depends upon the nature of the matters under discussion. Where the interview is concerned with the clarification of obscurities, the resolution of uncertainties, or putting the international application in order by clearing up a number of minor points, it will usually be sufficient if the examiner makes a note on the file of the matters discussed and the conclusions reached, or amendments agreed upon. If, however, the interview is concerned with reviewing more substantial matters, such as questions of novelty, inventive step, or whether the amendment introduces new subject matter, then a fuller note of the matters discussed may be made in the file (optionally using Form PCT/IPEA/428, Note on Informal Communication with the Applicant) for use in an additional written opinion (if any) or the international preliminary examination report and a copy of that note may, if appropriate, be sent to the applicant (optionally using Form PCT/IPEA/429).

Rule 66.3, 66.4, 66.4bis, 66.6

19.41_19.44 If a new objection as to substance is raised at an interview and no amendment to meet it is agreed upon at the time, the objection may be confirmed in an additional written opinion—or in the notification to the applicant with the records of the interview inviting the applicant, within the prescribed time limit, to respond, if he so wishes. The examiner should, however, keep in mind the time limit for the establishment of the international preliminary examination report (see paragraphs 19.10 and 19.11).

| 19.42 19.45 When the telephone is used to settle outstanding matters, the normal procedure should be for the examiner to telephone the applicant or the agent identifying the international application he wishes to discuss and requesting the applicant or agent to telephone back at a specific time. A note should be made on the file, giving particulars and identifying the matters discussed and any agreements reached.

49.4319.46 The records of interviews or telephone conversations should always indicate whether a response is due from the applicant or agent or whether the examiner wishes to issue an additional written opinion or establish the international preliminary examination report.

Establishment of the International Preliminary Examination Report

General

Article 35(1), and (2); Rule 66.4bis

49.4419.47 An international preliminary examination report should be issued within the prescribed time limit (see paragraph 19.10); in exceptional circumstances it may not be possible to meet this deadline (see paragraph 19.11), in which case the report is established as soon as possible thereafter. Except in the case of an international application in respect of which an affirmative opinion can be given initially to the three criteria referred to in Article 34(2)(c), this will follow one or more written opinions and possibly other communications with the applicant. In most cases this will follow the issuance of the written opinion by the International Searching Authority. If the examiner considers that the possibility exists of amending or correcting the international application to bring it into a form which meets the requirements of Article 33 (see paragraph 19.02), then the examiner should communicate to the applicant in his first written opinion, indicating that the International Preliminary Examining Authority is of the opinion that suitable amendments must be submitted within a stated period (see paragraph 17.57). All amendments, and arguments and requests for rectification of obvious mistakes submitted before the examiner has begun to draw up the report must be taken into account. Amendments and requests for rectification of obvious mistakes received later need not be considered for the purposes of the report.

<u>19.45</u> The international preliminary examination report giving the results of the international preliminary examination is prepared by the examiner by the completion of the prescribed Form (Form PCT/IPEA/409, entitled "International Preliminary Report on

Patentability (Chapter II of the Patent Cooperation Treaty)"). The examiner should keep in mind, when establishing the international preliminary examination report, that it is not to contain any statement on the question whether the claimed invention is or seems to be patentable or unpatentable according to any national law. Chapter 17 gives detailed guidance on the completion of the prescribed Form.

Determination of Time Limits

Article 35(1), 47(1)

19.46_19.49 When it is a matter for the Authority to determine applicable time limits referred to in the PCT, the examiner must consult all the factors relevant to the particular international application under consideration as well as the Regulations under the PCT which govern such time limits. The most important time limits for international preliminary examination so far as International Preliminary Examining Authorities are concerned, have been considered in more detail in the various chapters and paragraphs as follows:

- (i) translations of priority document: see Chapter 6 and Chapter 18;
- (ii) amendments: see Chapter 20 and paragraph 17.57;
- (iii) rectifications of obvious errors mistakes: see paragraph 19.39 and Chapter 8;
- (iv) response by the applicant to first written opinion: see Chapter 17;
- (v) restricting claims or payment of additional fees: see Chapter 10;
- (vi) furnishing priority documents: see Chapter 6;
- (vii) establishment of the international preliminary examination report: see paragraphs 19.10 and 19.11.

Rule 80

Failure of Applicant to Respond Within a Prescribed Time Limit

Rule 66.4bis

19.48_19.51 __If the applicant has not responded within a prescribed time limit, the effect of such lack of response differs as the circumstances of the case may require under the PCT and its Regulations. For instance, the international preliminary examination report may be established as if priority had not been claimed (see paragraph 17.29); the international preliminary examination report may be established on the "main invention" (see paragraph 17.62); the international preliminary examination report may be established with a negative determination (see paragraph 19.20 and Chapter 17). Normally, amendments, and arguments and requests for rectification of obvious mistakes need not be taken into account by the examiner for the purposes of a written opinion or the international preliminary examination report if they are received after he has begun to draw up that opinion or report (see paragraph 20.05).

Withdrawal of the Demand or All Elections

Rules 4.15(b), 90bis.4, 90bis.6

19.49_19.52 In the particular case where the applicant, by a signed notice sent to the International Bureau, withdraws the demand or all elections, the International Preliminary Examining Authority is notified of the withdrawal by the International Bureau, and the processing of the international application by the International Preliminary Examining Authority is discontinued. A notice of withdrawal must be signed by all the applicants of record in the international application or the agent, provided a power of attorney signed by all the applicants has been filed. The requirement for an agent to have a power of attorney cannot be waived for the purpose of withdrawal. Where two or more applicants filed a demand which elects the United States of America and where an applicant for the United States of America who is an inventor could not be found or reached after diligent effort, a notice of withdrawal need not be signed by that applicant ("the applicant concerned") if it is signed by at least one applicant and either:

(i) a statement is furnished explaining, to the satisfaction of the receiving Office, the International Bureau or the International Preliminary Examining Authority, the lack of signature of the applicant concerned; or

(ii) in the case of a notice or withdrawal of the demand, the applicant concerned did not sign the request but the requirements of Rule 4.15(b) were complied with.

If the notice of withdrawal is submitted by the applicant to the International Preliminary Examining Authority, the International Preliminary Examining Authority marks the date of receipt on the notice and transmits it promptly to the International Bureau. The notice is considered to have been submitted to the International Bureau on the date marked.

Chapter 20 Amendments

Amendment Prior to the Start of International Preliminary Examination

Amendment of the Claims Under Article 19

Rules 54bis.1(a)46.1, and 69.1(d)

20.01 The documents making up the international application referred to in paragraph 18.10 may include amendments of the claims filed by the applicant under Article 19, which must not go beyond the disclosure in the international application as filed (see paragraph 21.1021.10). These will be transmitted to the International Preliminary Examining Authority by the International Bureau. If a demand for international preliminary examination has already been submitted, the applicant should preferably, at the time he files the Article 19 amendments with the International Bureau, also file a copy of the amendments and the letter required under Rule 46.5(b) with the International Preliminary Examining Authority (Rule 62.2). In the event that the time limit for filing amendments under Article 19, as provided in Rule 46.1, has not expired and the demand includes a statement that the start of the international preliminary examination is to be postponed under Rule 53.9(b), the international preliminary examination should not start before:

- (a) the examiner receives a copy of any amendments made under Article 19, or
- (b) a notice from the applicant that he does not wish to make amendments under Article 19, or
- (c) the later of three two months from the transmittal of the international search by the International Searching Authority report and written opinion or of the declaration that no international search will be established or before the expiration of 2216 months from the priority date, whichever occurs first (See paragraphs 3.14 and 18.06 Rule 54bis).

Article 19 amendments are considered by the examiner only during the international preliminary examination procedure.

Amendment Under Article 34

Rule 66.1(a)

20.02 Amendments to the description, claims or drawings are made under Rule 66.8. These amendments may have been submitted to avoid possible objections of lack of novelty and/or lack of inventive step in view of the citations listed in the international search report, or other objections that may have been raised.

Articles 5, 6, 34(2)(b); Rule 66.1

20.03 The applicant is not restricted to amendments necessary to remedy a defect in his international application. However, any amendment submitted must not add subject matter which goes beyond the disclosure of the international application as originally filed (see paragraphs 20.10 to 20.19). Furthermore, it must not itself cause the international application as amended to be objectionable under the PCT. For example, the amendment should not introduce obscurity.

Making Amendments: General Considerations

20.04 Any change, other than the rectification of obvious <u>errorsmistakes</u>, in the claims, the description, or the drawings, including cancellation of claims, omission of passages in the description, or omission of certain drawings is considered an amendment. Any amendment to the international application must be submitted in the language in which the international preliminary examination is carried out.

Rule 66.1,66.4bis, 66.8(a)

20.05 The examiner need not take into account for the purposes of a written opinion or the international preliminary examination report any amendments. or requests for rectification of obvious mistakes he receives after he has begun to draw up that opinion or

report. The applicant may file an amendment to the description, the claims and the drawings in the prescribed manner, even if this is outside the time period set for reply in Rule 66.2(d). Since the examiner may begin to draw up the final report once the time period set for reply in Rule 66.2(d) expires, amendments filed after the expiration of the time period set in for reply in Rule 66.2(d) may or may not be considered. There may be situations where it is advisable, to the extent possible, to take such amendments or arguments into account, for example, where the international preliminary examination report has not yet been completed and it is readily apparent to the examiner that consideration of the late-filed response would result in the issuance of a favorable report.

Rule 66.1(a), and 66.8(a), (c)

20.06 Amendments to the claims, the description and the drawings must be made by filing replacement sheets when, on account of the amendments, the replacement sheet differs from the sheets previously filed. Amendments to the claims must be filed as a complete set to replace all the claims originally filed or previously amended under Articles 19 or 34, as the case may be. When amendments to the description, claims or drawings are made under Rule 66.8, the replacement sheets must be accompanied by a letter, which shall draws attention to the differences between the replaced sheets and the replacement sheets, shall indicate the basis for the amendments in the application as filed and should preferably also explain the reasons for the amendments.

Rule 66.8(ab)

20.07 In the particular case where the amendments cancel claims, passages in the description or certain drawings resulting in the cancellation of an entire sheet, the amendment must be submitted in the form of a letter canceling the sheet. That letter should preferably also explain the reasons for the amendments.

Rules 11.12. 11.14. 66.8(b)

20.08 It should be noted that, when a replacement sheet <u>or set of claims</u> is required under paragraph 20.06, the applicant must submit such sheet in typed form. However, replacement sheets <u>or set of claims</u> containing handwritten amendments may be allowed as well at the discretion of the examiner. In cases where the correction or amendment made by the applicant is minor, (for example, not more than six words), the International Preliminary Examining Authority may accept a copy of, <u>of sets of claims containing</u> the relevant sheet on which the correction or amendment is interlineated in typescript, if such interlineation is free from erasures, alterations and overwritings, and so long as the authenticity of this sheet is not in question and the requirements for clarity and good reproduction are met. The International Preliminary Examining Authority should invite the applicant to resubmit his amendments in proper form whenever compliance with these principles is lacking.

Appraisal of Amendments

Articles 5, 6, 19(2), 34(2)(b); Rule 66

- 20.09 The examiner makes sure that amendments filed do not add to the content of the application as filed, thus violating Article 19(2) or 34(2)(b). Furthermore, they must not itself cause the international application as amended to be objectionable under the PCT; for example, the amendment should not introduce obscurity. The examiner should consider as acceptable restriction of the scope of the claims or amendments that improve the clarity of the description or amendments to the claims in a manner clearly desirable, without changing their subject matter content or scope. An amended international application must, of course, satisfy all the requirements of the PCT including the matters listed in this chapter. However, especially when the claims have been substantially limited, the examiner should bear in mind that the following questions may require special consideration at the amendment stage:
- (i) *Unity of invention:* Do the amended claims satisfy the requirement of Rule 13? When considering this matter, paragraphs of Chapter 10 are applicable:
- (ii) Agreement of description and claims: If the claims have been amended, will the description require corresponding amendment to remove serious inconsistency between

them? For example, is every embodiment of the invention described still within the scope of one or more claims? (see See Chapter 5).

(iii) Conversely, are all of the amended claims supported by the description? (see See paragraphs 5.43 and 5.44). Also, if the categories of claims have been altered, the examiner may draw this to the attention of the applicant if it means that the title is no longer appropriate.

Additional Subject Matter

Rules 70.2(c), 70.16(b); Section 602(a)(iv)

- There is normally no objection to an applicant's introducing, by amendment, further information regarding prior art which is relevant, nor should the straightforward clarification of an obscurity, or the resolution of an inconsistency, be objected to. When, however, the applicant seeks to amend the description (other than references to the prior art), the drawings, or the claims in such a way that subject matter which extends beyond the content of the application as filed is thereby introduced, the international preliminary examination report must be established as if such amendment had not been made. The examiner indicates in the international preliminary examination report each sheet that contains subject matter which goes beyond the disclosure of the application as filed. In such cases the replacement sheets containing such amendments will be attached to the international preliminary examination report along with the accompanying letter as required under Rule 70.16(a) since they represent amendments which have been made, even though they are not considered for the purposes of the international preliminary examination report. If a first replacement sheet was acceptable but a second replacement sheet for the same numbered sheet contains subject matter that goes beyond the original disclosure of the application as filed, the second replacement sheet supersedes the first replacement sheet. In this situation, both the first and second replacement sheets are attached to the international preliminary examination report along with the accompanying letters as required under Rule 70.16(a) to ensure that elected Offices receive the version of the international application which is the basis of the international preliminary examination report and also the later amendments which were not considered for that purpose. In this case the superseded replacement sheet is marked "SUPERSEDED REPLACEMENT SHEET (RULE 70.16(b))".
- 20.11 Where amendments have been filed under Articles 19(1) and/or 34(2)(b), the question may arise whether a particular amendment proposed by the applicant goes beyond the disclosure of the international application as filed. In order to make this determination in situations where the amendment is filed in a different language than the language of the application as filed, the examiner should normally assume, in the absence of evidence to the contrary, that the original translation of the international application into the language of publication or, where a translation is required under Rule 55.2, into the language of that translation, is in conformity with the text of the original language of filing.

Articles 19(2), 34(2)(b); Rule 70.2(c)

- 20.12 An amendment should be regarded as introducing subject matter which extends beyond the content of the application as filed, and therefore unacceptable, if the overall change in the content of the application (whether by way of addition, alteration or excision) results in the skilled person being presented with information, which was not expressly or inherently presented in the application as filed even when taking into account matter which is implicit to a person skilled in the art in what has been expressly mentioned. The term "inherently" requires that the missing descriptive matter is necessarily present in the disclosure, and that it would be recognized by persons of ordinary skill. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.
- 20.13 The subject matter newly presented may be introduced by explicitly mentioning matter, which was either not previously mentioned at all, or only implied. For example, if in an international application relating to a rubber composition comprising several ingredients

the applicant seeks to introduce the information that a further ingredient might be added, then this amendment should normally be regarded as going beyond the disclosure in the application as originally filed. Likewise, if in an application which describes and claims apparatus "mounted on resilient supports," without disclosing any particular kind of resilient support the applicant seeks to add specific information that the supports are, or could be, for example, helical springs (see, however, paragraph 20.14), then the amendment should normally be regarded as going beyond the disclosure in the application as originally filed.

- 20.14 If, however, the applicant can show convincingly that the subject matter in question would, in the context of the claimed invention, be so well known to the person skilled in the art that its introduction could be regarded as an obvious clarification and, therefore, as not extending the content of the application, it is permissible. For example, if in the abovementioned case of the resilient supports the applicant were able to demonstrate that drawings, as interpreted by the person skilled in the art, showed helical springs, or that the person skilled in the art would naturally use helical springs for the mounting in question, then specific reference to helical springs should be regarded as permissible.
- 20.15 Where a technical feature was clearly disclosed in the original application but its effect was not mentioned or not mentioned fully, yet it can be deduced without difficulty by a person skilled in the art from the application as filed, subsequent clarification of that effect in the description might not contravene Article 34(2)(b).
- 20.16 Amendment by the introduction of further examples, for example, in the chemical field, should always be looked at very carefully, since *prima facie* any further example to illustrate a claimed invention may extend the disclosure of the international application as originally filed.
- 20.17 However, later-filed examples or statements of advantage, even if not allowed into the application, may nevertheless be taken into account by the examiner as evidence in support of the allowability of the claims in the application. For instance, an additional example may be accepted as evidence that the invention can be readily applied, on the basis of the information given in the originally filed application, over the whole field claimed (see paragraphs 5.52 and 5.53); or an additional statement of advantage may be accepted as evidence in support of inventive step (see paragraph 13.15). When such evidence is used by the examiner to support a positive conclusion on inventive step, a mention of this evidence should be made in the international preliminary examination report.
- 20.18 Care must also be taken to ensure that any amendment to, or subsequent insertion of, a statement of the technical problem solved by the invention meets Article 34(2)(b). For example, it may happen that, following restriction of the claims to meet an objection of lack of inventive step, it is desired to revise the stated problem to emphasize an effect attainable by the thus restricted invention but not by the prior art. It must be remembered that such revision is only permissible if the effect emphasized is one deducible by a person skilled in the art without difficulty from the application as filed (see paragraphs 20.15 and 20.16).
- 20.19 As indicated in paragraph 20.12, alteration or excision of the text, as well as the addition of further text, may introduce new subject matter. For instance, suppose a claimed invention related to a multi-layer laminated panel and the description included several examples of different layered arrangements, one of these having an outer layer of polyethylene, amendment either to alter the outer layer to polypropylene or to omit this layer altogether would not normally be regarded as permissible. In each case, the panel disclosed by the amended example would be quite different from that originally disclosed and hence the amendment would be considered as introducing new subject matter.

Lack of Support

20.20 Where subject matter is disclosed in a claim of the application as filed, but is not mentioned anywhere in the description, it is permissible to amend the description so that it

includes this subject matter as disclosed in that claim. However, consideration would still need to be given as to whether the description as amended provides the required support for the claims. If there is a contradiction or inconsistency between the claims and description, this will have to be resolved by amendment of either the claims or description. In some occasional circumstances, there may be a question of whether the claims provide sufficient disclosure to allow amendment of the description without adding matter that goes beyond the disclosure as filed or to provide full support. An amendment to include a negative limitation to overcome prior art may raise a lack of support issue.

20.21 An amendment to the claims or the addition of a new claim must be supported by the description of the invention as originally filed, and each claim limitation must be explicitly or inherently supported in the originally filed disclosure. Where such an amendment introduces a negative limitation, exclusion, or disclaimer, the amendment should be examined to determine whether it may raise a new matter issue. See the appendix to this chapter for examples. See paragraphs 20.10 *et seq.* for a discussion of what constitutes matter that goes beyond the description as originally filed.

Amendments to Translated Applications

Rules 55, 60.1(a) to (e)

20.22 If the examiner determines that an erroneous translation has been published or furnished under Rule 55.2 or 55.3, or that an amendment is not in the language on the basis of which the international preliminary examination is being conducted (see paragraphs 18.07 to 18.09), he may invite the applicant, at any time during the proceedings before the International Preliminary Examining Authority, to provide a translation of the amendment or to correct any such translation so as to bring it in line with the language of the text as filed and/or as published, as the case may be. If the applicant fails to supply a translation of the amendment within the time limit set in the invitation, the amendment is not taken into account for the purposes of the international preliminary examination.

Appendix to Chapter 20

New Matter

- A20.21 The International Preliminary Examining Authorities have divergent practices with regard to when a negative limitation, disclaimer, or exclusion will raise a new matter issue. Either of the alternative guidelines below may be relied upon by an International Authority as appropriate.
- A20.21[1] A negative limitation that is added in a new claim or by amendment will raise a new matter issue if the subject matter being excluded does not have support in the application as filed. For example, if the disclosure describes a genus of compounds, but does not provide support for any particular species within that genus, a negative limitation excluding a particular species would raise the issue of new matter.
- A20.21[2] A negative limitation or disclaimer with no basis in the application as filed is permissible where the limitation or disclaimer is added to overcome accidental anticipation by a reference or to exclude parts of a claim for reasons other than novelty, such as for lack of industrial applicability or insufficient disclosure.

PART VII QUALITY

Chapter 21 A-Common Quality Framework for International Search and Preliminary Examination

Introduction

21.01 International Searching Authorities and International Preliminary Examining Authorities are entrusted to apply and observe all the common rules of international search and examination. Although applicants can generally expect the International Searching and Examining Authorities to act in accordance with these Guidelines, due to the involvement of several States in the international search and examination process and to the multitude of personnel within the various Authorities, some variability is inherent, due to the involvement of several Authorities in the international search and examination process and to the multitude of personnel within the various Authorities, in the international search and examination process. At the same time, it is recognized that minimizing inconsistencies between or and within the International Searching and Examining Authorities is crucial to the unqualified acceptance of an Authority's work product by other Officesthe States.

<u>21.02</u> This chapter sets out the main features of a quality framework for international search and preliminary examination. It describes a minimum set of criteria that each <u>International</u> Authority <u>("Authority")</u> should use as a model for establishing <u>their its</u> individual quality scheme.

Rule 36.1(iv) and 63.1(v)

21.0221.03 Each Authority should establish and maintain a quality management system (QMS) which complies with the following requirements with regard to:

- 1. Leadership and policy
- 2. Resources
- 3. Management of administrative workload
- 4. Quality assurance
- 5. Communication
- 6. Documentation
- 7. Search process documentation

Additional Provisions:

- 8. Internal review
- 9. Reporting arrangements

1. Leadership and policy

21.0321.04 Top management of the each Authority is responsible for the development and implementation of a Quality Management System (QMS). Top management should establish a quality policy for the Authority and it should delegate responsibilities for the QMS and document these in an organizational chart.

21.0421.05 Management should ensure compatibility of its QMS with the requirements of these International Search and Preliminary Examination Guidelines.

<u>21.05</u>21.06 Management should ensure the effectiveness of the QMS and that the process of continual improvement progresses.

- <u>21.0621.07</u> Management of the Authority should communicate to its staff the importance of meeting treaty and regulatory requirements including those of this <u>standard-framework</u> and <u>of complying</u> with the Authority's QMS.
- 21.0721.08 Top management of the Authority or delegated officers should conduct management reviews and ensure the availability of appropriate resources. It should regularly review quality objectives and ensure that they are communicated and understood throughout the respective Authority.
- 21.0821.09 Top management or delegated officers of each the Authority will review its respective QMS at regular intervals. The minimum scope and frequency of such reviews and the frequency is are set out in Section 8, below.

2. Resources

- <u>21.0921.10</u> <u>An Each</u> Authority should be able to accommodate changes in workload and should have an appropriate infrastructure to support the search and examination process and comply with the QMS requirements and these <u>Search and Examination</u> Guidelines. <u>To those ends, the Authority should have:</u>
- -21.11 Each Authority should have s Sufficient human Human Resources:
- (i) A a quantity of staff sufficient to deal with the inflow of work and which maintains the technical qualifications to search and examine in the required technical fields and the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated;
- (ii) Aappropriately trained/skilled administrative staff at a level to support the technically qualified staff and facilitate the search and examination process, and for the documentation of records;

-21.12 Each Authority should have s Sufficient mMaterial rResources:

- (iii) Aappropriate equipment and facilities, such as IT hardware and software, to support the search and examination process;
- (iv) Ppossession of, or access to, at least the minimum documentation referred to in Rule 34, properly arranged for search and examination purposes, on paper, in microform or stored on electronic media;
- (v) <u>C</u>comprehensive and up-to-date instructions to help staff understand and adhere to the quality criteria and standards and follow work procedures accurately and consistently;

-21.13 Each Authority should have sSufficient tTraining rResources:

- (vi) Aan effective training and development program for all staff involved in the search and examination process to ensure they acquire and maintain the necessary experience and skills and are fully aware of the importance of complying with the quality criteria and standards; and
- <u>21.14 Each Authority should have oOversight oOver its rResources:</u>
- (vii) a system for continuously monitoring and identifying the resources required to deal with demand and comply with the quality standards for search and examination.

3. Management of aAdministrative wWorkload

- <u>21.1021.11</u> <u>The Each Authority</u> should have in place the following minimum practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification:
- (i) <u>Ee</u>ffective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and
- (ii) Aappropriate control mechanisms regarding fluctuations in demand and backlog management.

4. Quality aAssurance

- 21.1121.12 An Each Authority should have procedures regarding timely issue of search and examination reports of a quality standard in accordance with these Search and Examination Guidelines. Such procedures should include:
- (i) Aan effective internal quality assurance system for self-assessment, involving verification and validation and monitoring of searches and examination work for compliance with these Search and Examination Guidelines and channeling feedback to staff;
- (ii) Aan effective system of measurement and collection of data and reporting, and commitment to using it to ensure the continuous improvement of the established processes; and
- (iii) A-a system for verifying the effectiveness of actions taken to address deficiencies and to prevent issues from recurring.

Such procedures may also include the use of checklists, either to verify the quality standard of search and examination reports in accordance with these Guidelines before those reports are issued and/or to monitor that quality standard as part of a post-issue review process.

5. Communication

- 21.17 Inter-Authority ©Communication
- <u>21.13</u> To help identify and disseminate best practice among Authorities and foster continual improvement, each Authority should provide for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.
- 21.14 The Each Authority should nominate and make known to other Authorities the name of a quality contact person.
- 21.18 Communication and guidance to users:
- 21.15 The Each Authority should have in place a system for monitoring and using customer feedback including at least the following elements:
- (i) Aan appropriate system for handling complaints and making corrections, and taking corrective and/or preventative action where appropriate and offering feedback to users.
- (ii) A-a procedure for monitoring user satisfaction and perception and for ensuring their legitimate needs and expectations are met.
- (iii) Cclear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process which could be included on each Authority's web site as well as in guidance literature.
- - 21.19 Communication with WIPO and designated and elected Offices

<u>21.16</u> To help improve performance and foster continual improvement, each Authority should provide for effective communication with <u>WIPO the International Bureau</u> and designated and elected Offices to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

6. Documentation

- 21.1221.17 The QMS of the each Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity.
- 21.1321.18 Therefore the Authority should provide a reference for its staff and management in the form of a Quality Manual, which documents all the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In the manual it is to be indicated where instructions on the procedures to be followed may be found.
- 21.1421.19 The following list indicates the items which are considered to be the type of content of a Quality Manual:
- (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
 - (ii) the scope of the QMS, including details of and justification for any exclusions;
- (iii) the organizational structure of the Authority and the responsibilities of each of its departments;
- (iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;
- (v) the resources available for carrying out the processes and implementing the procedures; and
- (vi) A a description of the interaction between the processes and the procedures of the QMS.
- 21.1521.20 The following list indicates the types of records that each Authority should maintain:
 - (i) Aa definition of which documents are kept and where they are kept
 - (ii) Rresults of management review;
 - (iii) ‡training, skills and experience of personnel;
 - (iv) <u>Ee</u>vidence of conformity of processes, resulting products and services in terms of quality standards;
 - (v) Rresults of reviews of requirements relating to products;
 - (vi) Tthe search and examination processes carried out on each application;
 - (vii) Data allowing individual work to be tracked and traced;
 - (viii) Rrecords of QMS audits:
 - (ix) Aactions taken re. non-conforming product, e.g. examples of corrections;
 - (x) Aactions taken re. corrective action;
 - (xi) Aactions taken re. preventative action; and
 - (xii) Search process documentation as set out in Section 7.

7. Search process documentation

- 21.1621.21 For internal purposes the each Authority should document its search process which may include *inter alia*:
 - (i) The databases consulted (patent and non-patent literature);

 - (iii) [∓]the language(s) in which the search was carried out;
- (iv) Ţthe classes and class combinations searched, at least according to the IPC or equivalent; and
 - (v) Aalisting of all search statements used in the databases consulted.
- (vi) <u>Ee</u>ach Authority should further document at least for internal purposes special cases such as:
 - (vii) Limitation of search and its justification;
 - (viii) Lack of clarity of the claims; and
 - (ix) Llack of unity.

8. Internal review

- 21.1721.22 In addition to establishing a quality assurance system for checking and ensuring compliance with the requirements set out in its QMS, each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model and the extent to which it is complying with the QMS requirements and these Search and Examination Guidelines. The reviews should be objective and transparent so as to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year.
- 21.1821.23 It is open to each Authority to set up its own arrangements but the following is proposed as a guide to the basic components of an internal review mechanism and reporting system.
- 21.1921.24 The input to each review should include information on:
- (i) <u>G</u>conformity with the QMS requirements and these Search and Examination Guidelines;
- (ii) Aany corrective and preventative action taken to eliminate the cause of non-compliance;
 - (iii) Aany follow-up action from previous reviews;
 - (iv) The the effectiveness of the QMS itself and its processes;
- (v) F_feedback from customers, including designated and elected Offices as well as applicants; and
 - (vi) Rrecommendations for improvement.
- <u>21.2021.25</u> Suitable arrangements should be established for monitoring, recording and measuring compliance with the QMS requirements and these <u>Search and Examination</u> Guidelines.
- 9. Arrangements for authorities to report to the MIA
- 21.26 There are two stages in the reporting arrangements.

- (a) 21.29 Initial reports: Each Authority shall submit an initial report to the Meeting of International Authorities under the PCT (MIA) describing what it has done to implement a QMS based on the broad requirements set out in the present document. This would help identify and disseminate best practice among Authorities. MIA should then submit a general initial report on progress to the PCT Assembly.
- (a)(b) 21.30 Annual reports: Following the initial reporting in stage 1, annual reports shall be prepared by each Authority, identifying the lessons learned and actions taken and making recommendations in light of the review.
- 21.2121.27 The reports submitted by Authorities shall be made available by the International Bureau on WIPO's website.

10. Future developments

21.2221.28 Proposals for future changes to this the framework set out in this chapter should be made available by the International Bureau for comment by interested parties prior to adoption.

PART VIII CLERICAL AND ADMINISTRATIVE PROCEDURES

Chapter 22 Clerical and Administrative Procedures

Receipt of the Demand

Article 31(6)(a)

22.01 The International Preliminary Examining Authority receives the demand for international preliminary examination normally directly from the applicant. Alternatively the International Preliminary Examining Authority may receive the demand from the International Bureau, a Receiving Office, an International Searching Authority or a non-competent International Preliminary Examining Authority under Rule 59.3.

Determination of Competent International Preliminary Examining Authority and Marking of the Demand

Articles 31(6)(a), 32; Rule 59.3

22.02 Where the demand is filed with an International Preliminary Examining Authority, it checks the demand to establish whether or not it is a competent Authority to receive the demand according to the agreement established between the Authority and the International Bureau. If the determination is positive, the International Preliminary Examining Authority proceeds with the review of the demand as set forth in paragraphs 22.06 et seq. If the determination is negative, the non-competent International Preliminary Examining Authority indelibly marks the date of actual receipt of the demand in the space provided on the last sheet of the demand and transmits the demand, together with any accompanying documents or items, to the International Bureau for further handling and notifies the applicant of that fact. Form PCT/IPEA/436 is used for this purpose. Where the demand is filed with a receiving Office or an International Searching Authority, the Office or Authority follows the same procedure (but using Form PCT/RO/153 or PCT/ISA/234). Where the demand Form or a computer print-out used by the applicant does not comply with Section 102(h) or (i) of the Administrative Instructions, the procedure for correcting defects under paragraphs 22.24 et sea, applies.

Rule 59.3(a), (c), and (f)

The non-competent International Preliminary Examining Authority may, instead, 22.03 choose to transmit the demand directly to the competent International Preliminary Examining Authority. In such a case, if only one International Preliminary Examining Authority is competent, it transmits the demand to that Authority and notifies the applicant accordingly, using Form PCT/IPEA/436. If two or more International Preliminary Examining Authorities are competent, it must first invite the applicant to indicate, within the time limit applicable under Rule 54bis.1(a), that is, 3 months from the date of transmittal of the international search report and the written opinion under Rule 43bis.1(a), or the declaration referred to in Article 17(2)(a), and the written opinion under Rule 43bis.1(a), or 22 months from the priority date, or 15 days from the date of the invitation, whichever is later, to which one of those Authorities the demand should be transmitted (using Form PCT/IPEA/442). If the applicant responds to the invitation, the non-competent International Preliminary Examining Authority promptly transmits the demand to the competent Authority specified by the applicant and notifies the applicant accordingly. If the applicant does not respond, or responds after the expiration of the time limit, the non-competent International Preliminary Examining Authority declares that the demand is considered as if it had not been submitted and notifies the applicant accordingly, using Form PCT/IPEA/407444. If the demand is filed with the receiving Office, International Searching Authority or International Bureau, that body follows the same procedure specified above for the non-competent International Preliminary Examining Authority, except that the forms used are Forms PCT/RO/153, PCT/ISA/234 and PCT/IB/368, respectively.

22.04 In all the situations outlined in paragraphs 22.02 and 22.03, the non-competent International Preliminary Examining Authority, receiving Office, International Searching Authority or International Bureau refunds to the applicant any fees paid to it.

Rule 59.3(e)

22.05 If the International Preliminary Examining Authority receives the demand transmitted to it, under Rule 59.3, by a receiving Office, an International Searching Authority, the International Bureau or another International Preliminary Examining Authority which is not competent for the international preliminary examination of the international application, the competent International Preliminary Examining Authority considers that the demand was received on its behalf by the Office, Bureau or Authority transmitting on the date marked as the "actual date of receipt" on the last sheet of the demand.

Identification of the International Application

Rules 53.6, 60.1(b)

22.06 The International Preliminary Examining Authority checks whether the international application to which the demand relates can be identified, for example, by checking the name and address of the applicant, title of the invention, international filing date and international application number. If the determination is negative, the International Preliminary Examining Authority promptly invites the applicant to submit corrections using Form PCT/IPEA/404. If the corrections are submitted within the time limit fixed in the invitation, the demand is considered as if it had been received on the date on which the International Preliminary Examining Authority receives the corrections and the Authority indicates the date of receipt of the corrections on the first sheet of the demand and in the box for the adjusted date of receipt on the last sheet (see also paragraph 22.12). If the corrections are not submitted within this time limit, the demand is considered not to have been submitted and the International Preliminary Examining Authority so declares (Form PCT/IPEA/407).

Applicant's Entitlement to File a Demand

Article 31(2); Rule 54

22.07 The International Preliminary Examining Authority checks whether the applicant is entitled to file the demand. An applicant is entitled to file a demand if he is a resident or national of a Contracting State bound by Chapter II of the Treaty and if the international application was filed with a receiving Office of, or acting for, a Contracting State bound by Chapter II of the Treaty. Currently (as of January 1, 2004) all Contracting States are bound by Chapter II.

Article 31(2); Rule 54.2, 54.4; Section 614

- 22.08 If there are two or more applicants, it is sufficient if at least one of the applicants making the demand is a national or resident of a Contracting State bound by Chapter II of the Treaty, irrespective of the elected States for which that applicant is indicated (see also paragraph 22.34). If none of the applicants has the right to make a demand under Rule 54.2, the demand is considered by the International Preliminary Examining Authority as not having been submitted (Form PCT/IPEA/407). In addition, if there is little time remaining prior to the expiration of 19 months from the priority date, the applicant should be informed as quickly as possible so that the applicant can timely enter the national phase in any designated State where a notification in respect of the modification to Article 22(1), adopted by the PCT Assembly with effect from April 1, 2002, is still in force.
- 22.09 The international application must have been filed with the receiving Office of a Contracting State bound by Chapter II, or acting for such a State. Where the receiving Office acts for two or more Contracting States, at least one of the applicants who filed the demand must be a resident or national of a Contracting State bound by Chapter II for which the receiving Office acts.

Change in the Applicant

22.10 Where the applicant named on the demand is not the same as the applicant indicated on the request, the International Preliminary Examining Authority must check that the new applicant is entitled to make that demand.

Election of States

Article 37: Rule 53.7

The filing of a demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the Treaty.

Check of Particulars Affecting the Date of Receipt

Rules 53.1(a), 60.1(a), 61.1(a); Section 102(h), and (i)

- 22.12 Where, after checking of particulars affecting the date of receipt, as described in paragraph 22.06, a positive determination is made, the actual filing date is marked as date of receipt in the space provided on the first sheet of the demand. Where the demand Form or a computer print-out in compliance with Section 102(h) or (i) of the Administrative Instructions was not used by the applicant, the procedure for correcting defects described in paragraphs 22.24 *et seg.* applies.
- The International Preliminary Examining Authority notifies the applicant of the receipt of the demand (Form PCT/IPEA/402).

Checking Whether Demand Is Timely Filed

Rule 54bis

The International Preliminary Examining Authority checks to see that the demand is filed within three months from the date of transmittal of the international search report and the written opinion established under Rule 43bis.1, or of the declaration referred to in Article 17(2)(a), and the written opinion established under Rule 43bis.1, or 22 months from the priority date, whichever expires later. If the demand is filed later, the International Preliminary Examining Authority considers the demand as having not been submitted and issues a declaration to that effect by sending a copy of Form PCT/IPEA/407 to the applicant and the International Bureau. If the demand is timely filed, the International Preliminary Examining Authority notifies the applicant accordingly (Form PCT/IPEA/402).

Article 39(1)(a); Section 601

22.15 In the event that the national law of any designated State continues to be incompatible with the modification of the time limit for national phase entry under Article 22(1), adopted by the PCT Assembly with effect from April 1, 2002, and such State is designated, the International Preliminary Examining Authority promptly checks whether the demand is received within 19 months from the priority date. When the demand is received after 19 months from the priority date, the International Preliminary Examining Authority marks the appropriate check box on the last page of the demand and notifies the applicant and the International Bureau accordingly (Form PCT/IPEA/402) as quickly as possible so that the applicant can timely enter the national phase in any designated State where the notification in respect of the modification to Article 22(1) is still in force. Irrespective of whether the demand was received within 19 months from the priority date, the International Preliminary Examining Authority promptly notifies the applicant of the date of actual receipt.

Establishing the International Preliminary Examining Authority File

22.16 The International Preliminary Examining Authority, promptly upon receipt of the demand, establishes the file.

Section 605

22.17 Where the International Preliminary Examining Authority is part of the same national Office or intergovernmental organization as the International Searching Authority, the same file serves the purposes of international search and international preliminary examination.

- 22.18 Where the International Preliminary Examining Authority is not part of the same national Office or intergovernmental organization as the International Searching Authority or receiving Office in which the application was filed, the International Bureau will provide a copy of the international application or, where already published, a copy of the pamphlet (of the published international application), together with a copy of the international search report, when available, to the International Preliminary Examining Authority upon request. This is necessary in order for that Authority to process the demand and conduct international preliminary examination. If the international search report is not yet available, the International Bureau will send a copy of it promptly upon receipt thereof. The documents cited in the international search report can be collected from the International Preliminary Examining Authority's own search files or ordered from the International Searching Authority. Upon receipt of the demand or a copy thereof, the International Bureau will promptly transmit to that Authority, a copy of the written opinion established by the International Searching Authority.
- 22.19 A copy of any amendments under Article 19 and of any accompanying statement will be supplied by the International Bureau to the International Preliminary Examining Authority unless a copy has been submitted with the demand by the applicant or the applicant has reversed them (see paragraphs 18.04 and 18.06).

Transmittal of the Demand to the International Bureau

Rules 61.1, 90bis.4(a)

- 22.20 The International Preliminary Examining Authority either transmits the original demand and keeps a copy in its files or sends a copy to the International Bureau and keeps the demand in its files. The demand or the copy thereof must be transmitted to the International Bureau, even where it has been withdrawn by the applicant, where it has been considered to have been withdrawn, and where the applicant did not respond to the invitation (Form PCT/IPEA/442) to indicate the competent Authority to which the demand was to be transmitted. Where a demand has been transmitted to the competent International Preliminary Examining Authority under Rule 59.3, it is the Authority which is competent to receive the demand which proceeds under this paragraph (see paragraphs 22.02 to 22.05).
- 22.21 The transmittal must be effected promptly after receipt of the demand, generally not later than one month after receipt.

Rule 90.4, 90.5; Section 608

22.22 The International Preliminary Examining Authority normally sends to the International Bureau, together with the original demand, or copy thereof, any original separate power of attorney or any copy of a general power of attorney received. However, if the International Preliminary Examining Authority has waived the requirement for a power of attorney under Rule 90.4(d), but a separate power of attorney or copy of the general power of attorney is nevertheless submitted, it is not necessary to send a copy of that power of attorney to the International Bureau.

Article 34

22.23 The International Preliminary Examining Authority does not transmit with the demand to the International Bureau any amendments to the application under Article 34 or copies of amendments under Article 19.

Certain Defects in the Demand

Article 31(3); Rules 53, 55, 60

22.24 The International Preliminary Examining Authority checks the demand for the following defects (Form PCT/IPEA/404):

Rule 53.1(a)

(i) the demand is not made on the prescribed Form;

Article 31(3); Rules 53.2(b), 53.8, 60.1(a-ter)

(ii) the demand is not signed as provided in the Regulations (see paragraphs 22.28 to 22.32);

Article 31(3); Rules 4.4, 4.5, 4.16, 53.2(a)(ii), 53.4, 60.1(a-bis)

(iii) the demand does not contain the prescribed indications concerning the applicant (see paragraph 22.33);

Article 31(3); Rule 53.2(a)(iii), 53.6

(iv) the demand does not contain the prescribed indications concerning the international application (see paragraph 22.06);

Rules 4.4, 4.7, 4.16, 53.2(a)(ii), 53.5

(v) the demand does not contain the prescribed indications concerning the agent (see paragraph 22.35);

Rule 53.2(a)(i), 53.3

(vi) the demand does not contain a petition to the effect that the applicant requests that the international application be the subject of international preliminary examination under the PCT; Rule 53.3 indicates preferred words, but these are not essential. The petition is part of the printed demand Form (Form PCT/IPEA/401) and must also be contained in a demand presented as a computer printout;

Rule 55.1

- (vii) the demand is not in the language of publication of the international application or in the language accepted by the International Preliminary Examining Authority.
- 22.25 For corrections of certain defects in the demand, *ex officio* or upon invitation, see paragraphs 22.26 (*ex officio* corrections), 22.35 (indications concerning the applicantagent) and 22.37 (invitation to correct defects).
- 22.26 Many kinds of errors in the demand can be corrected by the International Preliminary Examining Authority *ex officio*, which means that the applicant need not and is not formally invited to make the correction himself. Where a correction is made *ex officio*, the International Preliminary Examining Authority makes the correction and enters in the margin the letters "IPEA." Where any matter is to be deleted, the International Preliminary Examining Authority encloses such matter within square brackets and draws a line between the square brackets, while still leaving the deleted matter legible. The International Preliminary Examining Authority informs the applicant of the correction made by sending him either a copy of the corrected sheet of the demand or by a separate notification (there is no special Form, but Form PCT/IPEA/424, which is for use where no other Form is applicable, could be used). Errors which may be corrected *ex officio* include, in particular, indications concerning the applicant and the agent designated in the demand. If the error is corrected by the International Preliminary Examining Authority after the original demand has been transmitted to the International Bureau, the International Preliminary Examining Authority notifies the International Bureau by sending it a copy of the corrected sheet of the demand.

Language

Rules 23.1(b), 55.2, 62bis.1

22.27 Where neither the language in which the international application is filed nor the language in which the international application is published is accepted by the International Preliminary Examining Authority, the applicant must furnish with the demand a translation of the international application into a language in which the international preliminary examination may be carried out, that is, a language which is both a language accepted by that Authority and a language of publication. This translation must include any element referred to in Article 11(1)(iii)(d) or (e) furnished by the applicant under Rule 20.3(b) or 20.6(a) and any part of the description, claims or drawings furnished by the applicant under Rule 20.5(b) or 20.6(a) which is considered to have been contained in the international application under Rule 20.6(b). Where a translation into such a language has already been

furnished to the International Searching Authority under Rule 23.1(b) and the International Preliminary Examining Authority is part of the same national Office or intergovernmental organization as the International Searching Authority, the international preliminary examination is carried out on the basis of that translation, unless the applicant furnishes a translation to the International Preliminary Examining Authority as outlined above. Upon request of the International Preliminary Examining Authority, the written opinion established by the International Searching Authority, when not in English or a language accepted by the International Preliminary Examining Authority, will be translated into English by or under the responsibility of the International Bureau. The International Bureau will forward a copy of the translation of the written opinion within two months from the date of request.

Signature

Rules 53.2(b), 60.1(a-ter)

22.28 Except as set forth in paragraph 22.30, the applicant must either sign the demand or submit a separate power of attorney or a copy of a signed general power of attorney, appointing an agent for the filing of the demand. If there are two or more applicants, it is sufficient that the demand be signed by one of them.

Rule 90.3, 90.4(d)

22.29 Where the agent signs the demand and a power of attorney has been filed earlier with the receiving Office, the International Searching Authority or the International Bureau or where the agent has been appointed in the request, no power of attorney need be submitted by the applicant to the International Preliminary Examining Authority. Where the agent signs the demand and the demand is filed with an International Preliminary Examining Authority which has not waived the requirement that a separate power of attorney be submitted to it, that International Preliminary Examining Authority confirms that the agent has been appointed to act before the International Preliminary Examining Authority if no power of attorney accompanies the demand or has already been filed with the receiving Office, the International Searching Authority, or the International Bureau. Where the International Preliminary Examining Authority is not the same Office as the receiving Office or the International Searching Authority, the International Preliminary Examining Authority may, until it is notified of or has reason to believe the contrary, assume that an agent who is indicated in the pamphlet publication of the international application and in the PCT Gazette has been duly appointed by the applicant.

Rule 90.4(d)

22.30 The International Preliminary Examining Authority may waive the requirement that a separate power of attorney or a copy of the general power of attorney be submitted to it. This waiver cannot cover the submission of a notice of withdrawal by an agent or common representative. Where an International Preliminary Examining Authority has waived the requirement for a separate power of attorney, the agent named in a demand may sign the demand even though no separate power of attorney has been filed with the receiving Office, the International Searching Authority, the International Preliminary Examining Authority or the International Bureau nor has the agent been appointed in the request.

Rule 90.1(c), and (d), 90.3(b), 90.4

22.31 The appointment of an additional or sub-agent for the procedure before the International Preliminary Examining Authority can be made in the demand or through a separate or general power of attorney. If the appointment is made in the demand which is signed by the applicant, no separate power of attorney need be submitted. If the demand is signed by an earlier appointed agent, no separate power of attorney from the applicant need be filed if the earlier appointed agent has the right to appoint sub-agents. If the demand is signed by the additional or sub-agent, a separate power of attorney need not be filed if the demand is filed with an International Preliminary Examining Authority which has waived the requirement for a separate power of attorney. Authorization to appoint may be assumed unless the power of attorney excludes appointing sub-agents. If a demand is signed by the additional agent, a separate power of attorney signed by the applicant, or his earlier

appointed agent who has the right to appoint sub-agents, must be filed where the International Preliminary Examining Authority has not waived the requirements that a separate power of attorney be submitted. If a separate power of attorney accompanies the demand or is later filed, the International Preliminary Examining Authority promptly transmits the original or a copy to the International Bureau. For the manner of inviting the correction of a missing signature, see paragraph 22.37.

Rule 90.2(a), and (b), 90.3(c)

22.32 A common representative is entitled to sign the demand with effect for all applicants. The agent of the common representative may also sign with effect for all applicants.

Indications Concerning the Applicant

Rules 4.4, 4.5, 4.16, 53.2(a)(ii), 53.4, 60.1(a-bis); Sections 115, 614

22.33 The demand must contain the prescribed indications concerning the applicant. The address must contain an indication of the country; the indication of the country by a letter code as part of the postal code is sufficient (for example, CH-1211 Geneva). Nationality and residence must be indicated by the name or the two-letter country codes of the State of nationality and State of residence; in case of a dependent territory (which is not a State), the name of the State on which the territory depends must be given as the indication of the residence. For the manner of indicating names of States, see Section 115 of the Administrative Instructions. If there are two or more applicants, it is sufficient that the address, nationality and residence are provided in respect of one of them who has the right to make a demand.

Section 614

22.34 For the decision whether the applicant has the right to make a demand it is decisive that the applicant had the right at the time the demand was filed. Where the demand does not contain the corresponding indications, or where the applicant made mistakes by giving indications which are not the indications required to support the right to file the demand, the omission or wrong indication may be corrected by the applicant if the International Preliminary Examining Authority is satisfied that the applicant had the right to file a demand at the time the demand was received. In such a case, the demand is considered as having met the requirements under Article 31(2)(a) as of the date when the demand with the mistakes in the indications was filed.

Indications Concerning the Agent

Rules 4.4, 4.7, 4.16, 53.5, 90.1

22.35 If an agent is named or appointed, the International Preliminary Examining Authority checks whether the indications correspond to those contained in the file. If the International Preliminary Examining Authority does not have information about the appointment, it checks whether the agent has been indicated in the publication of the international application, on the pamphlet or in the *PCT Gazette*, or checks with the International Bureau. In case of an appointment or naming of a new agent or an additional agent in the demand, the International Preliminary Examining Authority also checks whether the indications as to such an agent comply with Rules 4.4 and 4.16; Rule 4.7 applies *mutatis mutandis*. The International Preliminary Examining Authority may waive the requirement for a power of attorney.

Rule 90.1(c), and (d)

22.36 The International Preliminary Examining Authority may request the receiving Office, if necessary, to confirm that the agent has the right to practice before that Office (optionally using Form PCT/IPEA/410) if the agent does not have the right to practice before the International Preliminary Examining Authority.

Invitation to Correct Defects in the Demand

Rules 53, 55, 60.1(a), (a-ter), and (b)

22.37 If the International Preliminary Examining Authority finds one or more defects referred to in Rule 60.1(a) and (b), it invites the applicant to correct the defects within one month from the date of the invitation (Form PCT/IPEA/404). The International Preliminary Examining Authority notifies the International Bureau by sending it a copy of the invitation. Where the defect consists of the lack of the signature of at least one applicant (see paragraph 22.28), the International Preliminary Examining Authority may include with the invitation to correct, a copy of the last sheet of the demand which the applicant returns after affixing thereto the prescribed signature. Where the defect consists of the lack of the signature on the demand and the demand is filled with an International Preliminary Examining Authority which has waived the requirement for a separate power of attorney, the International Preliminary Examining Authority may include with the invitation to correct, a copy of the last sheet of the demand which the agent returns after signing.

Rule 60.1(c) and (d); Section 602(a)

- 22.38 Upon receipt of a letter containing a correction or accompanying a replacement sheet of the demand the International Preliminary Examining Authority marks on that letter and any accompanying sheets the date on which they were received. It verifies the identity of the contents of any replacement sheet of the demand with that of the replaced sheet (see paragraphs 22.40 and 22.41 for the consequences of this check. If the applicant complies with the invitation within the time limit, the demand is considered as if it had been received on the actual filing date provided that the demand as submitted permitted the international application to be identified. The International Preliminary Examining Authority marks in the upper right-hand corner of the replacement sheet, the international application number and the date on which the replacement sheet was received and, in the middle of the bottom margin, the words "AMENDED-SUBSTITUTE SHEET (RULE 60.1)." It keeps in its files a copy of any letter and any replacement sheet. It transmits any replacement sheet of the demand and a copy of any letter to the International Bureau. The International Preliminary Examining Authority undertakes the actions referred to in this paragraph not only where the corrections submitted by the applicant are timely received and satisfactory, but also where they are not and, consequently, the demand is considered as if it had not been submitted.
- 22.39 If the International Preliminary Examining Authority receives a replacement sheet of a sheet of the demand embodying a correction of a defect referred to in Rule 60.1(a), which was submitted by the applicant of his own volition without having been invited to correct a defect, the International Preliminary Examining Authority proceeds as outlined in the preceding paragraph.

Rule 60.1(a), (b)

- 22.40 The International Preliminary Examining Authority checks whether the defects referred to in Rule 60.1(a) have or have not been timely corrected. If the applicant complies with the invitation within the time limit, the demand is considered as if it had been received on the actual filing date provided that the demand as submitted permitted the international application to be identified. The one-month time limit for correction may be extended. If a correction of a defect is received after the expiration of the time limit for correction but before a decision is taken, the time limit for correction should be extended ex officio so that the said correction is considered as having been timely received.
 - Rule 60.1(b), and (c)
- 22.41 If the International Preliminary Examining Authority finds that any of the defects referred to in Rule 60.1(a), with the exception of those also referred to in Rule 60.1(d), have not been corrected or have not been timely corrected (see the preceding paragraph), it declares that the demand is considered as if it had not been submitted and notifies the applicant and the International Bureau (Form PCT/IPEA/407). If the date of receipt of the demand is changed, the International Preliminary Examining Authority notifies the applicant and the International Bureau (Form PCT/IPEA/402).

Rule 60.1(d)

22.42 If the International Preliminary Examining Authority finds that any of the defects referred to in Rule 60.1(d) have not been corrected or have not been timely corrected, it notifies the applicant and the International Bureau (Form PCT/IPEA/439).

Payment and Refund of Fees

Rule 57, 58

22.42 The International Preliminary Examining Authority calculates the amounts of the prescribed preliminary examination fee and handling fee. It also determines whether the fees have been paid and it notifies the applicant of any underpayment or overpayment (optionally using Form PCT/IPEA/403).

Rules 57.2(a), 58.1(b)

22.43 The amount of the handling fee, which is collected for the benefit of the International Bureau, is as set out in the Schedule of Fees. The amount of the preliminary examination fee, if any, is fixed by the International Preliminary Examining Authority.

Rules 57.3, 58.1(b)

22.44 The handling fee and the preliminary examination fee are payable within one month from the date on which the demand was submitted or 22 months from the priority date, whichever time limit expires later. Where the demand was transmitted to the International Preliminary Examining Authority under Rule 59.3, these fees are payable within one month from the date of actual receipt of the demand by that Authority or 22 months from the priority date, whichever time limit expires later. Where the International Preliminary Examining Authority decides to start the international preliminary examination at the same time as the international search, that Authority will invite the applicant to pay the handling fee and the preliminary examination fee within one month from the date of the invitation. The amount payable is the amount applicable on that date of payment. If, before the date on which those fees are due, the International Preliminary Examining Authority finds that no fees have been paid to it or that the amount paid to it is insufficient to cover them, it may invite the applicant to pay to it any missing amount (optionally using Form PCT/IPEA/403).

Rule 58bis.1(a), and (c), 58bis.2

Where, by the time the handling and preliminary examination fees are due, the International Preliminary Examining Authority finds that no fees were paid to it, or that the amount paid to it is insufficient to cover them, it invites the applicant to pay to it any missing amount, together with, where applicable, a late payment fee, as provided under Rule 58*bis.*2, within a time limit of one month from the date of the invitation (using Form PCT/IPEA/440). A copy of that invitation is sent to the International Bureau. However, if any payment is received by the International Preliminary Examining Authority before such invitation has been sent, that payment is considered to have been received before the expiration of the time limit referred to in paragraph 22.44.

Rule 58bis.2

22.46 If a late payment fee is charged, its amount is 50% of the amount of unpaid fees which is specified in the invitation, or, if the amount so calculated is less than the handling fee, an amount equal to the handling fee may be charged. The amount of the late payment fee must in no case exceed double the amount of the handling fee.

Rule 58bis.1(b). and (d)

22.47 Where the International Preliminary Examining Authority has sent an invitation under Rule 58*bis*.1(a) and the applicant has not, within the time limit of one month from the date of the invitation, paid in full the amount due, including, where applicable, the late payment fee, the International Preliminary Examining Authority declares that the demand is considered as if it had not been submitted, using Form PCT/IPEA/407. If the amount due is received before the demand is declared not to have been submitted, payment is considered to have been received before the expiration of the time limit referred to above and the

International Preliminary Examining Authority does not declare that the demand is considered as if it had not been submitted.

Rules 54.4, 57.64

22.48 The International Preliminary Examining Authority refunds the handling fee to the applicant if the demand is either withdrawn before it has been sent to the International Bureau or considered not to have been submitted because none of the applicants has the right to make a demand.

Transfer of Handling Fees to the International Bureau

Rule 57

22.49 The International Preliminary Examining Authority should, each month, transfer the handling fees collected during the preceding month to the International Bureau. When making the transfer, the International Preliminary Examining Authority indicates the exact amounts transferred, broken down according to the international application numbers of the international applications concerned, as well as the names of the applicants.

Use of Facsimile Machine, Telegraph, Teleprinter, Etc.

Rule 92.4(d), and (e)

22.50 Where the furnishing of the original of a document is required as confirmation by the International Preliminary Examining Authority of the document that was transmitted by facsimile, telegraph, teleprinter or other like means of communication, but the original of a document signed by the applicant or his agent is not received, within 14 days, an invitation is sent to the applicant inviting him to comply with the requirement within a time limit which must be reasonable (optionally using Form PCT/IPEA/434) (see paragraph 18.01). The original document does not need to be submitted as confirmation unless the original is required by the International Preliminary Examining Authority.

Rule 92.1(b), 92.4(g)(ii)

22.51 If the applicant does not comply with the invitation within the time limit, the International Preliminary Examining Authority notifies the applicant that the document is considered not to have been submitted (optionally using Form PCT/IPEA/438).

Irregularities in the Mail Service

Rule 82

22.52 For the applicable procedure in case of delay or loss in the mail or in case of interruption in the mail service, reference is made to Rule 82. Rule 82 applies also if a delivery service is used to the extent that the International Preliminary Examining Authority accepts evidence of the mailing of a document by a delivery service other than the postal authorities.

Computation of Time Limits

Rule 80

22.53 For details regarding the computation of time limits and dates of documents, reference is made to Rule 80.

Amendments Under Article 19

Article 19; Rule 53.9(a)(ii)

22.54 If the applicant indicates that any amendments under Article 19 are to be disregarded, the International Preliminary Examining Authority treats any such amendments as reversed and marks the relevant sheets of amendments accordingly.

Response to the Written Opinion

Section 602(a)

22.55 In response to an opinion, an applicant may file amendments with a cover letter. On receipt of these amendments, the International Preliminary Examining Authority indicates on the top right hand corner of the substitute sheets the application number and the date of

receipt. The International Preliminary Examining Authority marks the words "AMENDED SHEET" or their equivalent in the middle of the bottom margin of each sheet.

Rule 92.1(a), 92.2(a)

22.56 It should also be noticed that any paper submitted by the applicant in the course of international preliminary examination other than the international application itself, if not in the form of a letter, must be accompanied by a letter signed by the applicant. The letter should identify the international application to which it relates and be in the same language as the said application or in one of the languages authorized to be used by the International Preliminary Examining Authority. If these requirements are not complied with, the applicant should be informed as to the non-compliance and invited to remedy the omission within a time limit fixed in the invitation. The time limit should be reasonable in the circumstances, but no less than 10 days and no more than one month from the mailing of the invitation. If the omission is remedied within the time limit fixed in the invitation, the omission should be disregarded, otherwise the paper should be disregarded.

Rules 55, 60.1(a) to (e)

22.57 If it is determined that an erroneous translation has been published or furnished under Rule 55.2 or that an amendment is not in a language accepted by the International Preliminary Examining Authority, the applicant may be invited, at any time during the proceedings before the International Preliminary Examining Authority, to provide a translation of the amendment or to correct any translation of the international application so as to bring it in line with the language of the text as filed and/or as published, as the case may be. If the applicant fails to supply a translation of the amendment within the time limit set in the invitation, the amendment is not taken into account for the purposes of the international preliminary examination.

Transmittal of the International Preliminary Examination Report

Rule 71.1

- 22.58 The International Preliminary Examining Authority must on the same day:
- (i) transmit one copy of the international preliminary examination report (Form PCT/IPEA/409) and its annexes, if any, to the International Bureau under the cover of Form PCT/IPEA/415, and one copy of the report under cover of Form PCT/IPEA/416 to the applicant;
- (ii) place a copy of the notification, report and amendment/rectifications in the examination file; and
- (iii) where belated filing of Article 34 amendments means that such amendments have not been taken into account by the International Preliminary Examining Authority, notify the applicant of this fact, optionally using Form PCT/IPEA/432 (second check box action).

Withdrawal of the Demand or All Elections

Rule 90bis.4, 90bis.5

- 22.59 In the particular case where the applicant, by a signed notice sent to the International Bureau, withdraws the demand or all elections, the International Preliminary Examining Authority is notified of the withdrawal by the International Bureau, and the processing of the international application by the International Preliminary Examining Authority is discontinued. A notice of withdrawal must be signed by all the applicants of record in the international application or the agent, provided a power of attorney signed by all the applicants has been filed. The requirement for an agent to have a power of attorney cannot be waived for the purpose of any withdrawal.
- 22.59 ... Where two or more applicants filed a demand which elects the United States of America and where an applicant for the United States of America who is an inventor could not be found or reached after diligent effort, a notice of withdrawal need not be signed by that applicant ("the applicant concerned") if it is signed by at least one applicant and either:

i) a statement is furnished explaining, to the satisfaction of the receiving Office, the International Bureau or the International Preliminary Examining Authority, the lack of signature of the applicant concerned; or

If the notice of withdrawal is submitted by the applicant to the International Preliminary Examining Authority, the International Preliminary Examining Authority marks the date of receipt on the notice and transmits it promptly to the International Bureau. The notice is considered to have been submitted to the International Bureau on the date marked.

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