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PRACTICE GUIDELINES UNDER THE SUBSTANTIVE PATENT LAW TREATY

*prepared by the International Bureau*

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## INTRODUCTION

1. The present document contains a revised version of the draft Practice Guidelines under the Substantive Patent Law Treaty (SPLT), into which the contents of the Notes on the provisions of the draft Substantive Patent Law Treaty and the draft Regulations Under the Substantive Patent Law Treaty (document SCP/7/5) were merged. This combined document provisionally incorporates the whole contents of the former Notes into the Practice Guidelines. It is intended to provide a comprehensive set of explanation contained in the Notes and the draft Practice Guidelines in order to assist the SCP in deciding which issues should be contained in the Practice Guidelines and, which ones in the Notes, if any. The texts which were contained in the former Practice Guidelines (document SCP/7/4) are highlighted in this document.

2. The views expressed in the Standing Committee on the Law of Patents (SCP) at its seventh session from May 6 to 10, 2002, were taken into account when revising this document.

## PRACTICE GUIDELINES

Guidelines Under Article 1 and Rule 1  
(Details Concerning Abbreviated Expressions)

3. Article 1, item (i). The term “Office” includes both the national Office of any State which is a Contracting Party to the Treaty, and the regional Office of any intergovernmental organization which is a Contracting Party. For example, the Treaty will apply to the European Patent Office only if, the European Patent Organisation is a Contracting Party. The term also includes branch offices of such national and regional Offices. The reference to “other matters covered by this Treaty” covers the situation in which the Office of a Contracting Party is in charge of other procedures in respect of patents, for example, a post-grant opposition or the invalidation of a granted patent.

4. Article 1, item (v). The terms “earlier application filed with effect in a Contracting Party” are used in the Treaty and the Regulations to refer to the earlier applications which have prior art effect in a Contracting Party. Where the Contracting Party is a State, the earlier applications encompass certain national applications, regional applications (if applicable) and international applications under the Patent Cooperation Treaty (PCT) [which designate the Contracting Party] [the processing or examination of which has started in the Contracting Party under Article 30 or 40 of that Treaty]. However, where the Contracting Party is a regional patent organization, the earlier applications are regional applications as well as international applications under the PCT [which designate the Contracting Party] [the processing or examination of which has started in the Contracting Party under Article 30 or 40 of that Treaty]. As regards the expressions “a[n] ...application...filed with or for the Office of the Contracting Party” and “a regional application...filed with or for the Office of a regional patent organization,” reference is made to paragraph 17.

5. Article 1, item (vii). The term “claimed invention” is used in the Treaty and the Regulations, since it is more precise than the term “invention,” which is often used in relation to patents in a general sense. In short, the expression “claimed invention” refers unambiguously to the subject matter for which protection is sought as it is contained and defined in a claim. It may be noted that the words “claimed invention” are also used in the PCT in relation to substantive matters of patentability (see for instance PCT Articles 33 to 35).

6. Article 1, items (viii) and (ix). The term “applicant” and “patentee” are used in the Treaty and the Regulations to refer only to the person who is indicated as such in the records of the Office. Accordingly, any other person who might have, or purports to have, a legal claim of ownership or other rights is not considered an applicant or patentee for the purposes of this Treaty or the Regulations. The question of who may apply for a patent remains a matter for the applicable law of the Contracting Party concerned. Where the applicable law provides that a patent must be applied for in the name of the actual inventor or inventors, the “person who is applying for the patent” could be the inventor or joint inventors. Where a person is permitted under the applicable law to apply for a patent in place of an inventor who, for example, is dead, or legally incapacitated, that person is the “person who is applying for the patent.” “Another person who is filing the application” could, for example, under certain circumstances, be the inventor’s legal representative or sole heir in the United States of

America. Where the applicable law provides that an application may be submitted by any natural or legal person, the applicant is the person submitting the application. Where the applicable law of a Contracting Party provides that several persons may jointly be applicants or patentees, the term “applicant” or “patentee” is to be construed as including “applicants” or “patentees” (see Article 1, item (xiii)). “Another person who is prosecuting the application” could, in particular, be an assignee of record of the right, title and interest in an application, where the applicable law of a Contracting Party requires the patent to be applied for in the name of the actual inventor and also provides that such an assignee is entitled to conduct the prosecution of the application to the exclusion of the named inventor.

7. Article 1, item (x). The priority date of an application is the date of the earliest application on which priority is claimed, and is used for setting time limits. However, the priority date is not always the date that determines the prior art for a particular claim, for example, where the claim contains elements that were not included in the application in respect of which the earliest priority is claimed. The term “claim date” takes into account the situation where an application contains more than one invention contained each in different claims, and which may claim the priority of different earlier applications. This reflects the practice of many Offices, which consider each claim on a case-by-case basis. The claim date relates to a particular claimed invention, not to the application as a whole, and establishes the date for the determination of the patentability of the particular invention contained in the claim. Thus, different claimed inventions in an application may have different claim dates. The claim date of a claimed invention in an application is either the actual filing date of that application or, where a right of priority based on an earlier application has been claimed in accordance with the applicable law, the filing date of the earlier application containing the claimed invention. It follows from the words “priority is claimed in accordance with the applicable law” that the claimed invention in question is entitled to the priority under the applicable law, which should be in conformity with Article 4 of the Paris Convention. The term “filing date” means the filing date of an application, as provided for under the applicable law.

8. In order to use a consistent term to refer to the date on which the prior art is determined for each claimed invention, it is suggested to adopt the term “claim date.” This term is already used in Canadian law in the same sense (see sections 2 and 28.1 of the Canadian Patent Act (R.S. 1985, c. P-4)). The use of the term “claim date” also allows to avoid the use of the term “priority date” throughout the Treaty and the Regulations in relation to substantive examination. It is further to be noted that the term “priority date” is not used in Article 4 of the Paris Convention. Rather, the Paris Convention refers to a priority period for each earlier application referred to in the priority claim.

9. The second sentence of item (ix) covers the situation where a claim defines its subject matter in the alternative. The term “alternative” means, according to the Webster’s Collegiate Dictionary (tenth edition), “a situation offering a choice between two or more things only one of which may be chosen”. Therefore, the second sentence deals, within the context of the claimed subject matter, with the cases where a claim contains more than one element or step and each of those elements or steps is entitled to a different claim date. It covers both clear and self-evident alternatives, such as Markush-type claims, and the case where the claim contained in the earlier application covers only a part of the claimed invention defined by a broad expression.

10. Article 1, item (xi). Since the Treaty and the Regulations would also be applicable to divisional, continuation and continuation-in-part applications (see paragraph 19), for these particular types of applications, the term “claim date” must be defined as the claim date of the claim in the relevant parent application.

Guidelines Under Rule 2  
(Details Concerning Person Skilled in the Art)

11. The person skilled in the art as defined under this provision is a hypothetical person, who has general knowledge and ordinary skills to comprehend and use the prior art on the relevant date. This means that a person having ordinary skills in the art has at his/her disposal the ordinary means and capacity used by an ordinary practitioner in the relevant field to conduct experimentation and analysis. The general knowledge referred to in Rule 2 is the common knowledge in the art as prescribed in draft Article 1(xii). The general knowledge may be contained in handbooks or textbooks in a tangible form. However, it may also consist of unwritten knowledge well-known or commonly used in the field of the art concerned, for example, well-known laboratory techniques. In any event, the person skilled in the art shall not be deemed to possess any inventive capability in addition to the conditions set forth in Rule 2. The reference to the “relevant date” takes into account the fact that, in the cases relating to the disclosure, i.e., draft Articles 7(3)(b), 10(1) and 11(4)(a) and draft Rules 4(1)(vii), 10(iii) and 12, the relevant date is the actual filing date, while in the cases relating to the determination of inventive step (non-obviousness), i.e., draft Article 12(3) and draft Rule 15(2), (3) and (4), that date is the claim date. As regards the reference to the “relevant date” in draft Rule 14(1)(ii) and (2)(a), since it concerns the prior art relevant to the determination of novelty, that date is the claim date, provided that the knowledge which became available to the person skilled in the art after the date on which the relevant prior art was made available to the public should be disregarded for the determination of the scope of the relevant prior art. Where the relevant prior art is an earlier application referred to in Article 8(2), the knowledge which became available to the person skilled in the art after the filing date of the earlier application or, where applicable under draft Article 8(2)(b), the filing date of the previous application, should be disregarded. With respect to Rule 13(5)(ii) concerning the doctrine of equivalents, the relevant date is the date of alleged infringement.

12. The term “the relevant field of the art” may cover more than one field of the art, if the nature of the claimed invention suggests a link to other fields of the art. It is not necessarily limited to the specific field of the claimed invention, but may include the neighboring fields of the art as well as general (non-specific) fields dealing with general problems commonly applicable to the specific fields. The person skilled in the art may also refer to other fields which are neither neighboring nor general fields, as long as a person skilled in the art would be expected to take those fields into account in view of, in particular, the factors indicated in items (i) to (iii) below. In determining the prior art in the relevant field of the art, the following factors, in particular, shall be taken into account:

(i) the nature and the characteristics of the field or fields of the art to which the claimed invention relates;

(ii) the type of problems encountered in the art;

(iii) the prior art solutions to those problems.

In view of the previous explanations, a person skilled in the art may be deemed to have the knowledge of a team of persons, for example a research team or a number of persons skilled in different fields of the art.

13. The definition under this provision is applicable to the term “person skilled in the art” throughout the Treaty and the Regulations. However, the relevant information at his/her disposal may differ between the determination of novelty and inventive step (non-obviousness) and of sufficiency of disclosure. For novelty and inventive step (non-obviousness) purposes, the person skilled in the art makes that determination based on his/her knowledge of the prior art, while for sufficiency of disclosure purposes, the person skilled in the art knows the disclosure of the claimed invention in the application in addition to the prior art.

#### Guidelines Under Article 2 (Details Concerning General Principles and Exceptions)

14. Paragraph (1). This provision states, in express terms, the principle that the Treaty and the Regulations do not deal with any requirements related to infringement issues. The Treaty and the Regulations therefore apply, as a general rule, to questions of patentability and validity (during both the pre-grant and post-grant stages). As agreed at the sixth session of the SCP, however, the words “Subject to Article 11(4)” provide one exception to this principle: for the determination of the scope of protection conferred by patents, the provisions concerning the interpretation of claims (see draft Article 11(4) and draft Rule 13) shall be applicable. It is to be noted that the SPLT does not interfere with other types of laws, such as antitrust and unfair competition laws, or general rules relating to fraud.

15. Paragraph (2). A similar provision is contained in Article 73(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and in Article 4 of the PLT. The “essential security interests” of a Contracting Party which is an intergovernmental organization refers to the security interests of its member States.

#### Guidelines Under Article 3 and Rule 3 (Details Concerning Applications and Patents to Which the Treaty Applies)

16. Article 3, paragraph (1). In principle, and subject to paragraph (2), this provision applies the Treaty and the Regulations to national and regional applications which are filed with or for the Office of a Contracting Party and to patents for invention and patents of addition, which have been granted with effect for a Contracting Party. As regards international applications under the Patent Cooperation Treaty, the Treaty and the Regulations apply to international applications once they enter the “national phase.” No distinction is made between applications filed by, and patents granted to, nationals of Contracting Parties and applications filed by, and patents granted to, other nationals.

17. Items (i) and (ii). The expression “national applications ... which are filed ... for the Office of a Contracting Party” covers, in particular, national applications for a patent that are



filed with the Office of another State X for onward transmission to the Office of the Contracting Party. A regional application which designates State X is an application filed with the Office of the regional organization but not an application filed for the Office of State X. The expression “regional applications ... which are filed ... for the Office of a regional patent organization” covers, in particular, regional applications for a patent that are filed with the Office of a State X, which is a member State of a regional organization that is a Contracting Party, for onward transmission to the Office of that organization. Accordingly, where, for example, State X were party to the Treaty, but the European Patent Organisation (EPO) were not, the Treaty and the Regulations would apply to national applications filed with or for the Office of State X, but not to European applications, even if State X were designated. Conversely, if the EPO were party to the Treaty, but State X were not, the Treaty and the Regulations would apply to European applications, including those designating State X, but would not apply to national applications filed with or for the Office of State X.

18. The terms “applications for patents for invention” and “applications for patents of addition” are to be construed in the same sense as these terms in PCT Article 2(i). Accordingly, the Treaty and the Regulations do not apply to the applications listed in that Article other than applications for patents for invention and applications for patents of addition, namely, applications for inventors’ certificates, utility certificates, utility models, certificates of addition, inventors’ certificates of addition, and utility certificates of addition. However, a Contracting Party is free to apply some or all of the provisions of the Treaty and the Regulations to such other applications, even though it is not obliged to do so. Similarly, the Treaty and the Regulations do not apply to applications for “plant patents” or “design patents” which are not patents for invention, although they do apply to applications for patents in respect of plants which are inventions, for example plants which are the result of genetic engineering.

19. Subject to paragraph (2), the Treaty and Regulations apply to all types of applications for patents for invention and patents of addition, including divisional applications and applications for continuation or continuation-in-part of an earlier application. It is to be noted that these items do not regulate the types of national or regional applications that a Contracting Party shall accept; this remains a matter for the applicable law of the Contracting Party concerned.

20. However, the Treaty and the Regulations do not apply to applications for patent term extension, for example, in respect of patents for pharmaceutical products under the laws of Japan, the United States of America and the European Community, since these are not applications for the grant of a patent. Similarly, they do not apply to applications for patent term adjustment, for example, as in the United States of America, in respect of the determination of additional patent term for delays in the issuance of a patent. In addition, they do not apply to an application for the conversion of an application for a European patent into a national application for one or more designated States since this is a request for a different type of treatment rather than an application for the grant of a patent. However, the Treaty does apply to the application once it has been converted to a national application, if the country concerned is party to the Treaty. A Contracting Party is free to apply some or all of the provisions of the Treaty and Regulations to any type of applications not covered by items (i) and (ii), although it is not obliged to do so.

21. Item (iii). Under this item, the provisions of the Treaty and Regulations apply to international applications for patents of invention and patents of addition under the PCT which have entered the “national phase” in a national or regional Office.
22. Item (iv). The Treaty and the Regulations apply both to national and regional patents granted by the Office of a Contracting Party and to patents granted on behalf of a Contracting Party by another Office, in particular, the regional Office of an intergovernmental organization, irrespective of whether that intergovernmental organization is party to the Treaty. For example, if State X referred to in paragraph 17, were party to the Treaty, the Treaty and the Regulations would apply both to patents granted by the Office of State X and to patents granted by the European Patent Office in so far as they have effect in State X, irrespective of whether the EPO were party to the Treaty. If the EPO were party to the Treaty, the Treaty and the Regulations would apply to all European patents for the purposes of any procedures before the European Patent Office, for example, the revocation of patents in opposition proceedings, even if State X were not party to the Treaty.
23. The terms “patents for invention” and “patents of addition” are to be construed in the same sense as those expressions in PCT Article 2(ii). Accordingly, the Treaty and the Regulations do not apply to patents which are listed in that Article other than patents for invention and patents of addition, namely, inventors’ certificates, utility certificates, utility models, certificates of addition, inventors’ certificates of addition, and utility certificates of addition (see also paragraph 18). However, a Contracting Party is free to apply some or all of the provisions of the Treaty and the Regulations to such other patents, even though it is not obliged to do so. In addition, the Treaty and the Regulations apply to patents for inventions and patents of addition granted on international applications.
24. Article 3, paragraph (2) and Rule 3. The types of applications and patents excepted under this paragraph are contained in draft Rule 3. In particular, the Treaty and the Regulations would not apply to provisional applications for patents for inventions and for patents of addition. However, a Contracting Party is free to apply some or all of the provisions of the Treaty and the Regulations to such other applications, even though it is not obliged to do so.

Guidelines Under Article 4  
(Details Concerning Right to a Patent)

25. This provision deals with the question of who has the right to a patent.
26. Paragraph (1). The basic principle provided by the Treaty is that the right to a patent shall belong to the inventor or to his successor in title. The term “inventor” means the person who actually invented the claimed subject matter. Therefore, a person who is not a true and original inventor is not considered as the “inventor.” The term “successor in title” covers any natural person or legal entity who, pursuant to the applicable law, is entitled to the right to a patent by virtue of transfer of the right from the inventor, such as through assignment, employment contract, donation, inheritance, bankruptcy and the like. The representative of a deceased or legally incapacitated inventor (or his successor in title) is not covered by this provision, since such a representative would, in general, not act in his own name, but in the name of the person he/she represents.

27. Paragraph (2). According to this provision, a Contracting Party is free to decide how it wishes to regulate the right to a patent in the case of employee's inventions and commissioned inventions.

28. Paragraph (3). This paragraph contains the applicable rules under the Treaty concerning the right to a patent where several inventors have jointly made the invention. In such a case, the inventors may agree on how the right to the patent shall be divided among them by way of, for example, a contract. In the absence of such an agreement, each inventor would have an equal and undivided right to the patent.

#### Guidelines Under Article 5 (Details Concerning Application)

29. Paragraph (1). This paragraph contains a list of the different parts an application must contain. The terms "where they are necessary for the understanding of the claimed invention" in item (iv) are not the same as the words "where required" used in Article 3(2) of the PCT, but are in line with PCT Article 7(1). The intention is to make it clear that they are not meant to allow Offices to require drawings, but rather to allow applicants to submit such drawings where this appears necessary for the understanding of the claimed invention. The term "drawings" in item (iv) shall be construed as including photographs and other forms of graphic representations using new technologies.

30. Paragraph (2)(a). This paragraph provides for the interface between the draft SPLT, the PLT and the PCT. Detailed explanations are contained in document SCP/6/5 ("Study on the Interface between the SPLT, the PLT and the PCT"). In principle, the requirements under the PCT relating to the request, description, claims, drawings and abstract, both formality requirements and substantive requirements, are incorporated by reference into the SPLT. However, if the PLT, the SPLT or the Regulations under those Treaties provide any other requirements different from or additional to the PCT requirements concerning the request, description, claims, drawings and abstract, the former shall apply. In particular, draft Rules 4 and 5 of the SPLT provide further requirements concerning the description and claims which are not identical to the PCT requirements.

31. In accordance with Rule 5.2 of the PCT, nucleotide and/or amino acid sequence listings are part of the description. Therefore, the requirements concerning such sequence listings under the PCT are incorporated by reference into the SPLT unless otherwise provided for in the SPLT.

32. Paragraph (2)(b). This provision ensures the freedom of a Contracting Party to provide requirements relating to form or contents of an application which are, from the viewpoint of applicants, more favorable than those referred to in paragraph (2)(a). It is modeled after Article 2(1) of the PLT.

33. Paragraph (3). This paragraph contains the generally accepted principle that the abstract shall only serve informational purposes, and shall, in particular, not be used for the purposes of interpreting the claims, determining the sufficiency of the disclosure or the patentability of the claimed invention. In the same context, attention is further drawn to draft Article 10(2)

relating to the disclosure. The SPLT does not regulate the question of who should establish the abstract. Therefore, the Office of a Contracting Party is free to establish the abstract itself or to amend the abstract, or to choose any figures that better characterize the claimed invention *ex-officio*.

Guidelines Under Rule 4  
(Further Requirements Concerning Contents and Order of Description  
Under Article 5(2))

34. This Rule provides further requirements concerning the contents and order of the description which are not identical to the PCT requirements and, therefore, constitute exceptions under draft Article 5(2). For reference, Rule 5.1 of the PCT provides the requirements concerning the manner of description of PCT international applications.

35. It follows from the wording of paragraph (1) that, as long as an applicant prepares the description with the contents in the manner and the order as prescribed in paragraph (1), the description would meet the requirement with respect to the contents of the description in any Contracting Party. In addition, according to paragraph (2), a Contracting Party shall accept the contents of the description presented in a manner or an order different from the one that is prescribed in paragraph (1), where such a different manner or a different order would afford a better understanding, or a more economical presentation, of the claimed invention. It goes without saying that, by all means, the substantive patentability requirements as set forth in draft Articles 10 to 12 must be complied with. Reference is also made to draft Articles 13 and 14, according to which the failure to comply with the requirements under Rule 4 shall be a ground for the refusal of the application, but may not be a ground for the invalidation or revocation of the patented claim or patent.

36. Paragraph (1), item (iii). In view of providing adequate flexibility for applicants in drafting the description on the one hand and adequate support for the efficiency of offices' operation on the other, it is suggested that, as a general rule, the claimed invention may be described in any terms as long as the substantive patentability requirements as set forth in draft Articles 10 to 12 are complied with. However, the so-called "problem-and-solution approach," which has been applied in many, but not all, cases because of its practicality, is presented as a preferable way of describing the invention. The Office of a Contracting Party could not refuse an application only because the "problem-and-solution approach" was not used to describe the claimed invention.

37. Paragraph (1), item (vi). The description of any mode (not necessarily the best mode contemplated by the applicant) for carrying out the claimed invention shall be furnished under this item.

38. Paragraph (1), item (vii). Since an applicant shall comply with the requirement concerning industrial applicability/utility under Article 12(4), he/she should demonstrate how that requirement is satisfied by way of indicating explicitly in the description the way(s) the claimed invention is useful or industrially applicable. Such an indication, however, is not necessary if a person skilled in the art can clearly understand the industrial applicability/utility of the claimed invention without any explicit indication.

39. Paragraph (2). The words “a different manner” are intended to also cover the cases where additional contents, which are not provided under paragraph (1), are included in the description, or where not all the contents under paragraph (1) are included in the description.

Guidelines Under Rule 5  
(Further Requirements Concerning Claims Under Article 5(2))

40. This Rule provides further requirements concerning the claims which are not identical to the PCT requirements and, therefore, constitute exceptions under draft Article 5(2). For reference, Rule 6 of the PCT provides the requirements concerning claims in respect of PCT international applications. It goes without saying that, in any event, the substantive requirements under draft Articles 10 to 12 (which include the requirement that the claims should be clear and concise under Article 11) shall be complied with. Reference is made to draft Articles 13 and 14, according to which the failure to comply with the requirements under Rule 5 shall be a ground for the refusal of the application, but may not be a ground for the invalidation or revocation of the patented claim or patent.

41. Paragraph (1). It follows from the words “whole numerals” that the numbering is not necessarily limited to Arabic numerals.

42. Paragraph (2). The meaning of the terms “features” and “limitations” are explained in Rule 1(c)(i) and (ii), according to which the term “feature” means the characteristics of the claimed invention as a whole which show the peculiar or prominent aspects of the invention, and the term “limitations” shall be considered as the specific elements or steps (depending on whether the claimed invention is a product or a process) which serve to form the claimed invention. The limitation may have both technical and non-technical aspects.

43. Paragraph (3). According to this provision, an applicant has the option to draft the claims either in two parts or in a single part.

44. Paragraph (4)(a). A reference to the description or any drawings in a claim is allowed where it is absolutely necessary, since, in some cases, such a reference may be necessary for a clear description of the claimed invention.

45. Paragraph (4)(b). Graphs may be contained in the claims, since they constitute pictorial representation of tables. However, no claim may contain drawings, since the drawings, which constitute general graphic representations, may not be appropriate to define the boundaries of the claim.

46. Paragraph (4)(c). In accordance with draft Rule 13(3), any reference signs to the applicable part of the drawing shall not be construed as limiting the claim.

47. Paragraph (5).<sup>1</sup> [Reserved]

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<sup>1</sup> The text of this paragraph will be added once the results of the discussions in the Working Group on Multiple Invention Disclosures and Complex Applications are known.

Guidelines Under Article 6 and Rule 6<sup>2</sup>  
(Details Concerning Unity of Invention)

[48. Draft Article 6 contains the widely accepted principle of unity of invention. The terms “the claims in the application” make it clear that the claims as such must fulfill the requirement of unity of invention, since they define the invention.

49. The essential purpose of the requirement of unity of invention is to facilitate the administration and the search of applications. Accordingly, reference is made to draft Articles 13 and 14, according to which the failure to comply with the requirement of unity of invention shall be a ground for the refusal of an application, but may not, if a patent has been granted on an application that does not comply with that requirement, be a ground for the invalidation or revocation of the patented claim or patent. In other words, failure to comply with the requirement can and needs only be corrected at the application stage. At that stage, the sanction for non-compliance is the refusal of the grant of a patent unless the claimed invention is restricted through the elimination of certain claimed subject matter. The subject matter so eliminated may then be included into one or more “divisional” applications.

50. An objection of lack of unity should only be made when lack of unity seriously disturbs the procedure and, if made, it should be made as soon as possible, that is, normally at the latest at the stage of the first examination based on the prior art. At a later stage of procedure, it should not be raised unless as a consequence of amendment of claims or for other clearly justified reasons.

51. Draft Rule 6, paragraph (1) contains the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in an application. According to that method, unity of invention will exist only when there is a certain relationship among the inventions involving one or more of the same or corresponding “special technical features.” The terms “special technical features” contained in Rule 4(1) of the 1991 Draft, have been replaced by a description of those terms, originating from the last sentence of Rule 4(1) of the 1991 Draft and PCT Rule 13.2.

52. Draft Rule 6, paragraph (2) is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in draft Rule 7(1)) remains the same regardless of the form of claim used.

53. This provision does not prevent an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or setting up a claims fee system applicable in that Office.]

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<sup>2</sup> The text of these Guidelines should be reviewed once the results of the discussions in the Working Group on Multiple Invention Disclosures and Complex Applications are known.

Guidelines Under Article 7 and Rule 7  
(Details Concerning Observations, Amendment or Correction of Application)

54. Paragraph (1)(a). This provision obliges the Office to provide, where it intends to reject or refuse an application based on the fact that the application does not meet any requirements provided under Article 13(1), at least one opportunity to make observations on the intended rejection or refusal and to subsequently remedy such non-compliance by way of, for example, an amendment or a correction. The Office cannot reject or refuse the application on the grounds of non-compliance with certain requirements, unless at least one opportunity to comply, within the time limit prescribed in draft Rule 7, with each and every of those requirements has been given to the applicant. It is to be noted that this provision does not require the Office to check the application as regards the compliance with all the requirements under the Treaty and the Regulations before the grant of a patent. Concerning the scope of amendments and corrections permitted, reference is made to paragraph (3) (see paragraphs 60 and 62). Where, despite the opportunity to amend or correct the application, the application still fails to comply with the requirements, the consequence of such non-compliance is provided in draft Article 13 (see paragraphs 148 to 150).

55. It is to be noted that, as far as formality requirements are concerned, the PLT provides that the Office shall notify the applicant and shall give at least one opportunity to comply with certain formality requirements. For example, where the filing date requirements under PLT Article 5(1) and (2) are not complied with, according to PLT Article 5(3), the Office shall notify the applicant, giving the opportunity to comply with any such requirements.

56. Paragraph (1)(b). This provision provides an exception to the obligation of an Office under subparagraph (a) as far as divisional, continuation and continuation-in-part applications are concerned: where, in the case of divisional, continuation or continuation-in-part applications, the opportunity to make observations and to correct or amend such applications has already been granted in respect of the parent application for remedying a certain error or defect, and the same error or defect was nevertheless not corrected and is still contained in the divisional, continuation or continuation-in-part application, the Office does not need to give a further opportunity for such correction or amendment, although it may do so at its own discretion.

57. Paragraph (2). According to paragraph (1), an applicant has the possibility to make observations and to make amendments and corrections following a notification from the Office on the non-compliance with any requirements under Article 13(1). In addition, this provision permits an applicant to subsequently remedy any non-compliance with the requirements on his own initiative up to the time when the application is in order for grant. The expression “when the application is in order for grant” is to be understood as the time when the Office completes the technical preparation of the notification that the application is in order for grant and that the required fee for grant and/or printing, if any, is due. Once these preparations of the notification are completed, i.e., when the notification is ready to be sent by the Office, the Office would not need to allow the applicant to make an amendment or correction. Abandoning a claim would be considered to be an amendment of the application.

58. However, where the Office provides a substantive examination by its own or through the Office of another State or intergovernmental organization, it may, except for clear mistakes under paragraph (3)(b), further limit the period during which the applicant may

amend or correct the application on his own initiative. This covers the cases where the Office of a Contracting Party utilizes the results of search or examination made by other Offices in order to grant patents or refuse patent applications filed with the Office of the Contracting Party. The words “substantive examination” under this provision are to be understood as an examination of a patent application with respect to at least one of the following requirements: novelty, inventive-step/non-obviousness, industrial applicability/utility, patentable subject matter and sufficiency of disclosure. “The first substantive communication from the Office” may be, for example, a communication from the Office to the applicant notifying the Office’s finding with respect to the non-compliance with any substantive requirements after, in particular, the substantive examination. It may also be a communication that the application is in order for grant and that the required fee for grant is due. Once the substantive examination has started, allowing the applicant to amend or correct the application on his/her initiative at any time may run counter an effective procedure to process patent applications. For example, a substantive examiner may, while conducting search and examination in respect of a claim, receive an amendment to that claim initiated by the applicant, which would oblige the examiner to repeat the whole search and examination process.

59. Since paragraph (2)(a) only deals with the right of the applicant to amend or correct the application, paragraph (2)(b) expressly provides that, if the applicable law so permits, the applicant may amend or correct the application on his own initiative at a later stage than is provided in paragraph (2)(a). Concerning the scope of amendments and corrections permitted, reference is made to paragraph (3) (see paragraphs 60 to 62).

60. Paragraph (3)(a). This provision is based on the principle that the applicant should not obtain patent protection for something which he did not disclose as of filing date. The consequence of the failure to comply with this requirement is provided in draft Article 13(1)(iii) (see paragraphs 148 and 149). The phrase “the disclosure in the description, the claims and any drawing on the filing date” includes matters that had been disclosed in the claims, description, and drawings on the filing date, but subsequently deleted during the prosecution of the application before the Office. The provision does not allow for the possibility to amend the description, the claims, the abstract and any drawings on the basis of what had been disclosed in the abstract as of the filing date, since the general rule established in Article 5(3) would apply, i.e., that the abstract shall serve information purposes only. Further, where an application claims the priority of a previous application, the provision does not allow an amendment or correction on the basis of what had been disclosed in the previous application, but was omitted from the application claiming the priority on the filing date, except in the case of the correction of a clear mistake. However, this paragraph does not prevent the applicant from amending the application by adding newly discovered references to the prior art, since such references would not extend the disclosure of the invention.

61. This paragraph does not cover the amendment and correction of the request, since that matter is expressly covered by PLT Article 6. An amendment or correction is considered to be going beyond the disclosure on the filing date, if the changes made to the disclosure of the invention, by way of addition, alteration or excision, result in the presentation of information which is not, for a person skilled in the art, directly and unambiguously derivable from the disclosure on the filing date. The phrase “included in the missing part of the description or the missing drawing, in accordance with the Patent Law Treaty” is necessary, since Article 5(6)(b) of the Patent Law Treaty provides that, under certain conditions, part of the



description or a drawing, which was omitted from the application as filed, could be included in the application later without having any effect on the filing date.

62. Paragraph (3)(b). Since the relevant person for the determination of the term “clear mistake” is a person skilled in the art on the filing date, clear mistakes would also cover mistakes of a technical nature, such as mistakes in chemical or mathematical formulas, if they were clear to a person skilled in the art on that date. The expression “person skilled in the art” is contained in draft Rule 2 (see paragraphs 11 to 13). In accordance with draft Article 16, in order to determine whether the mistake is a clear one, any evidence may be taken into account.

Guidelines Under Article *7bis*  
(Details Concerning Changes in Patents)

63. During the course of post-grant opposition or revocation proceedings, a new item of prior art which affects the patentability of the patented invention may be discovered. In that case, the patentee may wish to make changes in the patent in order to avoid the invalidity of his patent on the basis of the newly discovered prior art. On the other hand, for the purpose of legal certainty, it may not be feasible if a patent owner is allowed to make any changes on his patent after grant. Draft Article *7bis* provides certain conditions that the patentee could correct and/or amend his patent after grant.

64. Paragraph (1). As a general rule, a competent authority shall, upon request by the patentee, make changes in the patent, where the change would limit the scope of the claims, i.e., the extent of the protection conferred by the patent. However, a Contracting Party may refuse certain requests for changes in patents, where the patentee seek to narrow the claims so as to avoid invalidity on the basis of the item of prior art of which he was aware at a time when he could still amend or correct the application before the Office.

65. Paragraph (2). The patentee has a right to request a competent authority to make changes in the patent, which is a correction of clear mistakes. The term “clear mistake” should be understood in the same meaning as the one in draft Article 7(3)(b), i.e., a mistake shall be considered clear only where what is corrected would have been clearly wrong, and the correction would have been clear, to a person skilled in the art on the filing date (see paragraph 62).

66. Paragraph (3). This provision provides an option for a Contracting Party to allow the patentee to make changes in the patents in order to correct mistakes other than clear mistakes. Since this paragraph is an optional provision, a Contracting Party is free to apply it only to certain kind of mistakes, for example, mistakes made in good faith. However, once a Contracting Party decides to apply Article *7bis*(3), then it is obliged to apply two conditions which are contained in the proviso thereof, which takes into account of legal certainty of granted patents for third parties.

67. Paragraph (4). This provision is based on a principle that the patentee should not extend his exclusive rights over what he did not disclose as of filing date. Except in the case of correction of clear mistake under paragraph (2), the change in patents should not be permitted, if the change would result in the disclosure contained in the patent going beyond the disclosure contained in the description, the claims and any drawings on the filing date, or

included in the missing part of the description or the missing drawing, in accordance with the Patent Law Treaty. Reference is made to draft Article 7(3) which provides similar provision as regards amendments or corrections of the description, the claim, the abstract and any drawings in an application (see paragraphs 60 to 62).

Guidelines Under Article 8 and Rules 8 and 9  
(Details Concerning Prior Art)

68. Definition of Prior Art. The definition of prior art is of fundamental importance for the determination of patentability, since novelty and inventive step are examined on the basis of existing art, i.e., prior art. According to draft Article 8(1), first, the prior art with respect to the subject matter of a particular claim shall consist of all information which has been made available to the public anywhere in the world, before the claim date of such claim. Therefore, information made available on the same day, even though earlier than the time of filing of the claim in question, would not form part of the prior art. The expression “information” is to be understood as encompassing anything which can be captured by the five human senses through, for example, hearing, reading, study or instruction.

69. Second, the prior art shall consist of information that has been made available to the public in any form, whether it is in written form or not (see draft Rule 8(1) and paragraph 70). Consequently, for example, no Contracting Party may exclude from the prior art information that has been made available to the public by oral presentation, regardless of the country in which the presentation was made. Third, in accordance with the reference to draft Article 8(2), the prior art with respect to a certain claimed invention shall also include earlier applications that are filed with effect in the same Contracting Party before, but are published after, the claim date of that claimed invention (reference is made to the fact that prior art includes earlier applications claiming priority, if a previous application on which the right of priority is based has a filing date that is earlier than the claim date of that claimed invention), although the contents of the earlier application have not been made available to the public before the claim date. Fourth, in accordance with the reference to draft Article 9, information which meets the conditions of that Article is not considered to be prior art, even if that information has been made available to the public before the claim date.

70. Form of Prior Art. Draft Rule 8(1) obliges a Contracting Party to accept, as prior art under draft Article 8(1), any information that has been made available to the public in any form, including written form, electronic form, oral communication, display or use. Use may consist of producing, offering, marketing or exploiting a product, or offering or marketing a process or its application, or applying the process. Marketing may be effected, for example, by sale, offering for sale or exchange. Display may take the form of, for example, demonstrating a product or process in public or on television. Information that has been made available to the public through communication by electronic means, in particular via an electronic database or the Internet, also forms part of the prior art. Since this is not an exhaustive list, other forms of making available information to the public would be covered by this provision as well.

71. Information Made Available to the Public. Draft Rule 8(2)(a) provides for the interpretation of the words “made available to the public” under draft Article 8(1). It follows from the explicit language of draft Article 8(1) that, if the relevant information was actually

accessed by the public, and therefore, made available to the public, it forms part of the prior art. In addition, if there is a reasonable possibility that the information could be accessed by the public, it would also form part of the prior art.

72. The means by which the information was made accessible may offer some guidance on the interpretation of the words “a reasonable possibility that the information could be accessed by the public.”

(a) *By oral communication:* The information shall be deemed to be made available to the public if the information was unconditionally brought to the knowledge of the public through oral communication, such as a lecture or by means of radio or sound reproduction equipment (e.g., tapes and records).

(b) *By display or through use:* The information shall be deemed to be made available to the public if, on the relevant date, it was possible for the public to gain knowledge of that information through the display or the use of the medium. For example, if a person sells an object unconditionally to the public without limitation or restriction, or injunction or obligation of secrecy, the object shall be deemed to be made available to the public, since the buyer acquires unlimited possession of any knowledge which may be obtained from that object. Whether the information is considered to be available to the public is determined by the extent of control placed on its access by the person initially possessing the information.

(c) *In written form:* A document shall be regarded as made available to the public if, at the relevant date, it was possible for the public to gain knowledge of the contents of the document. Therefore, the public shall have not only the possibility of gaining access, in the technical sense, to the information contained in the document, but also the possibility of acquiring possession of such information. Whether the absence of an index or a catalogue of the information constitutes inaccessibility of the information to the public or not shall be determined in accordance with this principle.

(d) *Via an electronic database or the Internet:* The availability of information disclosed via an electronic database or the Internet shall be considered in the same manner as other forms of disclosure, i.e., whether it was reasonably possible for the public to gain knowledge of the information concerned or not. Accordingly, where the information disclosed on the Internet was made available to a limited circle of people, it is considered being made available to the public, provided no obligation to maintain secrecy was imposed. In order to determine whether the information disclosed on the Internet was made available on a particular date or not, the following factors, in particular, shall be taken into account: (i) public availability of the URL; (ii) possibility of search by a search engine; (iii) credibility of the web site.

73. As illustrated above, the “reasonable possibility” implies that the public should not be required to make excessive efforts in order to access to the information. Similarly, it implies that the public’s access to the information is legitimate. In other words, if the public needs to break a law in order to gain an access to the information, that information is not deemed to be reasonably accessible to the public.

74. “Public”. Draft Rule 8(2)(b) provides for the interpretation of the word “public” for the purposes of the definition of “prior art.” It follows from the words “any person” that the

public may be one or more persons who does not need to be a person skilled in the art and who, therefore, does not necessarily have the capability of understanding the prior art in the relevant field. It may be a single person. However, such person (or persons) must not be bound by a confidentiality obligation, and, therefore, must be free to disseminate the information to others, whether he (they) understand(s) the information or not. Thus, where information was made available to a limited circle of persons, as long as these persons are free to disclose the information and, therefore, to pass the knowledge to others, they fall under the term “public” under this provision.

75. Evidence. In accordance with draft Article 16, evidence may be submitted to the Office in order to demonstrate that the information concerned qualify as prior art. Such evidence may include the establishment of the date of disclosure and the contents of the disclosed information, or the existence of a reasonable possibility that the public could access the information. What constitutes evidence is left to the applicable law of Contracting Parties. It may consist of written evidence, testimonial evidence or any other kind of evidence allowed under the law of Contracting Parties.

76. Date of Availability to the Public. Draft Rule 8(3) aims at harmonizing the determination of the date on which the information was made available to the public for the purposes of prior art, where only the year or the month, but not the date, is specified. It follows from this provision that, in such a case, the last day of the year or the month should be considered as the date on which the information was made available to the public. However, a Contracting Party would be free to consider any evidence which establishes another date as the date on which the information was made available to the public.

77. Prior Art Effect of Earlier Applications. Draft Article 8(2) provides that the prior art with respect to a certain claim also consists of earlier applications filed with effect in the same Contracting Party, the filing date (or where applicable, the priority date) of which is earlier than the claim date of that claim, to the extent that the earlier application, or the patent granted on the earlier application, is published subsequently by the competent authority on or after such claim date. More precisely, draft Article 8(2)(a) deals with the cases where the filing date of an earlier application is earlier than the claim date of a claimed invention under consideration, and draft Article 8(2)(b) deals with the cases where the earlier application claims priority and where a previous application on which the priority is based has a filing date earlier than the claim date of the claimed invention under consideration. It goes without saying that, if the earlier application is published before the claim date of the claimed invention under consideration, it forms part of the prior art under draft Article 8(1). The earlier applications referred to in this provision form part of the prior art for the purpose of the determination of novelty, but not of inventive step. What constitutes an “earlier application filed with effect in a Contracting Party” is defined in draft Article 1(v). Where the Contracting Party is a State, an earlier application filed with effect in the Contracting Party means: (i) a national application filed with or for the Office of the Contracting Party; (ii) if the Contracting Party is a member of a regional patent organization, a regional application in which protection is sought in the Contracting Party; and (iii) an international application under the PCT [which designates the Contracting Party][which has entered the so-called national phase]. Where the Contracting Party is a regional organization, an earlier application filed with effect in the Contracting Party means: (i) a regional application filed with or for the Office of the Contracting Party; and (ii) an international application under the PCT [which designates the Contracting Party] [which has entered the so-called national phase].

78. Although the contents of an earlier application have not been made available to the public before the claim date of the claim under consideration, that application forms part of the prior art in order to avoid any possibility of double patenting, since the subject matter disclosed in the earlier application as of the filing date could lead to a separate patent. In addition, since the whole contents of the earlier application is published later, if the subject matter of the claim contained in the later application is not new having regard to the earlier application, that claim would not add any new contribution to the existing art.

79. The expression in draft Article 8(2)(b) “subject matter that is contained in both that earlier application and that previous application” does not mean that the subject matter has to be literally identical in both applications or that it has to be contained in a specific part of the application (for example the claims). It rather means that the main elements or features of the subject matter must be clearly identifiable, for a person skilled in the art, in both the earlier application and the previous application as a whole.

80. Draft Rule 9 provides further conditions to be fulfilled for an earlier application to be considered as part of the prior art under draft Article 8(2). First, the “whole contents” of the earlier application, that is, the claims, description and any drawings, of the earlier application shall be considered as prior art. Second, the prior art consists of the whole contents of an earlier application as of the filing date. This means that the subject matter which had been contained in, for example, the description as of the filing date, but was subsequently deleted during the prosecution of the application before the Office, also forms part of the prior art.

81. According to draft Article 3(1), the provisions of this Treaty and the Regulations shall apply to applications for patents for invention and for patents of addition, including divisional, continuation and continuation-in-part applications of these applications. However, where a Contracting Party provides any other titles of protection for an invention under the applicable law of the Contracting Party, such as a utility model, a short-term patent or an innovation patent, draft Rule 9(1)(b) obliges that Contracting Party to consider earlier applications filed under these titles of protection as part of the prior art under draft Article 8(2), provided that the other conditions under draft Article 8(2) and draft Rule 9 are met. However, if the Contracting Party does not prohibit double protection of the same invention by more than one title of protection, that Contracting Party is not obliged to consider earlier applications filed under other titles of protection as part of the prior art. Plant patents and design patents are not considered to be “other titles of protection for an invention.”

82. Draft Rule 9(3) covers the situation where the earlier application is no longer pending before the Office on the date of its publication. In view of the period which is necessary for the preparation of the publication and for the administrative procedure, there could be cases where the earlier application is still published despite its withdrawal, abandonment or refusal before the publication date. Further, there could be other cases where the earlier application had been erroneously published despite the fact that it was already withdrawn, abandoned or refused before the publication date. This provision therefore provides that, if the earlier application has been published even if it was no longer pending with no rights outstanding before the date of its publication, the earlier application shall not be considered prior art for the purposes of draft Article 8(2). On the other hand, where the earlier application was withdrawn or abandoned, was considered withdrawn or abandoned, or was rejected on or after

the date of its publication, that earlier application shall be considered as prior art, provided it was still pending before the publication date.

83. Draft Rule 9(4) obliges a Contracting Party to provide the so-called “anti-self-collision.” Although the whole contents of an earlier application shall be considered as prior art in accordance with draft Rule 9(1), if an applicant has claimed invention X in the earlier application, and the same applicant claims invention Y, which has been disclosed in the description or the drawings of the earlier application, in the subsequently filed application, the earlier application shall not form part of the prior art with respect to the latter application. In addition, where a Contracting Party allows internal priority, the applicant would have the possibility to claim the internal priority and to withdraw the earlier application. In the case of internal priority, the applicant may file a subsequent application within one year from the filing date of the earlier application, while the introduction of the anti-self-collision would allow the applicant to file a subsequent application by the time of publication of the earlier application (for example, 18 months from the filing date of the earlier application), which is normally longer than the internal priority period.

84. It follows from the words “or the inventor identified in” that the benefit of this paragraph excluding self-collision would be available also in the cases where the inventor named in two applications is the same, but the applicants of these applications are different because, for example, the inventor changed employer. The term “inventor” means the true inventor who has the right to the patent.

85. The effect of the phrase “at the filing date of the application under examination” is that this paragraph excluding self-collision would not be applicable in the cases where the applicants were not originally the same, but became the same as a consequence of, for example, an assignment.

86. The phrase “one and the same person” means that, where there are more than one applicant, or inventor, all the applicants, or inventors, of the earlier application and the application under examination must be the same. Further, the term “same claimed invention” means that the main elements or features of the claimed invention must be clearly identifiable for a person skilled in the art, as being contained in both applications taken as a whole.

#### Guidelines Under Article 9 (Details Concerning Information Not Affecting Patentability (Grace Period))

87. In accordance with Article 8, in principle, all information which has been made available to the public anywhere in the world in any form before the claim date shall constitute prior art. However, under certain circumstances, such a broad definition of prior art may run counter to the objective of a patent system, i.e., to strike an appropriate balance between the inventor and the general public. For example, it may not be justified if any disclosure, even if it was beyond the control of the inventor, leads to a loss of rights. Inventors may need to disclose the invention as soon as it is realized (even before the claim date, since it needs some time to prepare a patent application) to potential future partners or investors in order to develop the invention further. Under other circumstances, public research organizations, universities and certain firms may wish to disclose the results of their research to the public as early as possible, which may facilitate access to research results for

third parties. Therefore, draft Article 9 provides certain kinds of disclosures which do not affect patentability, even if the disclosure was made before the claim date. It is important to establish a uniform grace period at the international level so that a disclosure made under certain conditions at one place would not affect the patentability in other countries.

Otherwise, the applicant would be obliged to file patent applications before the public disclosure with the Offices which do not recognize the grace period. Further, even if Offices recognize the grace period, if the duration of the period is different among different Offices, the applicant would be forced to prepare an application on the basis of the shortest grace period, and would need to be familiar with different rules under different national/regional laws.

88. Paragraph (1). This provision provides the duration and the calculation of the grace period and the kinds of applicable disclosures. The words “the information was made available to the public anywhere in the world in any form” in the preamble shall be interpreted in the same manner as the corresponding text in draft Article 8(1). Therefore, the grace period may be invoked on the basis of a disclosure made in written form, in electronic form, by oral communication, by display or through use or in any other form. For example, the information may be disclosed through a presentation at an exhibition and through public experimental use. Further the provision is applicable to both intentional and unintentional disclosures, i.e., disclosures made by mistake[, except in the case of Article 9(1)(ii)(a)].

89. The words “with effect under Article 8(2) on a date during” cover the cases where an earlier application has a prior art effect under draft Article 8(2). In such a case, draft Article 9(1) applies if the filing date of the earlier application (in the case of draft Article 8(2)(a)), or the filing date of the previous application (in the case of draft Article 8(2)(b)), is within the period of [12][6] months preceding the claim date of the claimed invention to which the grace period applies.

#### *Duration and calculation of the grace period*

90. The duration of the grace period is [12][6] months from the claim date. Therefore, where an application claims priority in accordance with the applicable law, the grace period starts from the filing date of the earliest application whose priority is claimed and which contains the claimed invention (see draft Article 1(ix)). At the international level, in cases where the disclosure was made during the 12 months preceding the filing date of the previous application for which priority is claimed, if the grace period were calculated from the filing date of the subsequent application claiming priority, the applicant would not be able to enjoy the benefit of the grace period in respect of the subsequent application. This would mean that, in practice, where priority is claimed, it would not be possible to invoke the effects of the grace period based on a disclosure made before the original filing date.

#### *Kinds of disclosure*

91. The disclosures that would trigger the grace period could be made by the inventor (see draft Article 9(1)(i)), by an Office (see draft Article 9(1)(ii)) or by a third party which obtained the information directly or indirectly from the inventor (see draft Article 9(1)(iii)).

92. As regards the disclosure by a third party, the acquisition of the information or the disclosure of the information by the third party may occur either with or without the

knowledge or consent of the inventor (e.g., a breach of a confidentiality agreement). Similarly, it may be legal or illegal act (e.g., against the law relating to the test data of medicinal product).

93. Concerning the disclosure by an Office, the provision deals with the cases where (i) the information contained in another application filed by the inventor was disclosed, or had the effect of being disclosed in the cases of earlier applications under draft Article 8(2), by the Office during the grace period, and (ii) the information contained in an application filed without the knowledge or consent of the inventor by a third party was disclosed, or had the effect of being disclosed in the cases of earlier applications under Article 8(2), by the Office during the grace period. [As regards the first case, the grace period provisions apply where another application filed by the inventor was made available to the public by the Office (for example, published or laid open to public inspection) during the grace period, although the Office should not have done so. Therefore, the grace period provisions are applicable only where the application was disclosed to the public due to a mistake made by the Office.] [As regards the first case, the grace period provisions apply where another application filed by the inventor was made available to the public by the Office (for example, published or laid open to public inspection) during the grace period. Therefore, the grace period provisions cover any earlier applications filed by the inventor, which were publicly disclosed during the grace period.] The second case is applicable to both cases where the third party obtained the information directly from the inventor and filed a patent application, and where the third party, who filed a patent application, obtained the information indirectly from the inventor, such as through another person who acquired the information directly from the inventor.

94. Paragraph (2). The phrase “at any time” means that the effect of paragraph (1) can be claimed at any stage of the patent granting procedure or thereafter, for example, during invalidation proceedings. It would prevent third parties from raising, during invalidation proceedings, the prior art effect of a publication made by the inventor.

95. Paragraph (3). If the applicability of the grace period is contested either by the Office or by the third party, a person who invokes the effect of the grace period has the burden of proving that he is entitled to enjoy such effect. It follows from the wording of this provision that a Contracting Party is free to require, under the applicable law, evidence as proof of the identity of the information disclosed and the date of disclosure. This is in line with Article 11(3) of the Paris Convention concerning temporary protection afforded to patentable inventions in respect of goods exhibited at official or officially recognized international exhibitions.

96. Paragraph (4). It follows from the words “or before” that the provision covers the cases where a person had the right to a patent only before, but no longer on, the filing date of the application concerned (for example, the case of an assignment of that right).

97. Paragraph (5). This provision introduces intervening rights of third parties, who were using the invention or had started effective and serious preparations for such use, in good faith, between the date on which the invention, or information related to it, was made available to the public under paragraph (1) and the claim date. The party enjoying such intervening rights has the right to use (or to continue to use) the invention for the purposes of his/her business. A Contracting Party is, however, free to provide any remuneration mechanism for such use. For the purpose of this provision, the use of the invention consists



of any acts which would otherwise be considered as infringement under the applicable law, such as making, using, offering for sale, selling or importing for these purposes the invention. As regards the limitation to the claim date, reference is made to Article 4B of the Paris Convention, which states that third-party rights or any right of personal possession cannot be acquired during the priority period based on any of the acts referred to in that provision.

Guidelines Under Article 10 and Rule 10  
(Details Concerning Enabling Disclosure)

98. Article 10, paragraph (1). In addition to the so-called patentability requirements such as novelty, inventive-step (non-obviousness) and industrial applicability (utility), the claimed invention shall be fully disclosed in the application in such a manner as to allow a person skilled in the art to carry out the invention. Where the application refers to biologically reproducible material which cannot otherwise be disclosed in the application to meet the requirements prescribed in this paragraph, those requirements shall be considered to be complied with by a deposit of such material. Details concerning the deposit of biologically reproducible material are prescribed in draft Rule 11 (see paragraphs 106 to 109). The notion of “a person skilled in the art” is prescribed in draft Rule 2 (see paragraphs 11 to 13).

99. The second sentence of this paragraph clarifies the phrase “sufficiently clear and complete for the invention to be carried out by a person skilled in the art.” First, the disclosure is aimed at a person skilled in the art. This person shall, if necessary, use its general knowledge to supplement the information contained in the application (see draft Rule 2). Second, the disclosure must allow a person skilled in the art to both make and use the claimed invention. Therefore, if the disclosure of a claimed invention, for example, of a chemical compound or biological material which is isolated and purified, allows a person skilled in the art to reproduce such chemical compound or biological material, but is not sufficient to teach how it can be used, such a disclosure does not comply with the requirement under draft Article 10. Third, 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. Factors to be considered in order to assess the absence of “undue experimentation” are listed in draft Rule 10 (see paragraphs 101 to 105). Fourth, it follows from the phrase “as of the filing date” that the disclosure shall 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 filing date, not at the time of the examination or the grant of the patent.

100. Article 10, paragraph (2). For the purposes of assessing sufficiency of disclosure, the description, claims and drawings shall be examined on the basis of the disclosure made in the description, claims and drawings on the filing date, as amended and corrected under the applicable law. In accordance with draft Article 5(3), the abstract shall not be taken into account for the purpose of determining sufficiency of the disclosure. The sufficiency of disclosure shall be assessed on the basis of the claims, description and drawings as a whole. Therefore, where a claimed invention is sufficiently disclosed in the claims, description and drawings, but the description and drawings alone do not disclose the invention in a sufficiently clear and complete manner, the enablement requirement under draft Article 10 is met. However, in this case, the requirement concerning the relationship of the claims to the

disclosure under draft Article 11(3), i.e., that the claims shall be fully supported by the disclosure of the description and drawings, may not be met.

*Undue Experimentation*

101. Draft Rule 10 provides a non-exhaustive list of factors to be considered when assessing whether “undue experimentation” is required in order to carry out the invention on the basis of the disclosure in the application. Those factors are the following:

102. Item (i). The breadth of the claims is relevant to the determination of undue experimentation, since a person skilled in the art must be able to make and use 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 make and use part of the claimed invention.

103. Items (ii) and (iii). The nature of the claimed invention, i.e., 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.

104. Items (iv) and (v). “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 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.

105. Item (vi). 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.

Guidelines Under Rule 11  
(Details Concerning Deposit of Biologically Reproducible Material)

106. Paragraph (1). This provision establishes the legal effect of a deposit of biologically reproducible material referred to in an application. The deposit shall be considered part of the description to the extent that the requirement[s] regarding sufficiency of disclosure under draft Article 10 [and the relationship of claims to the disclosure under draft Article 11(3)] cannot otherwise be complied with so that it would be taken into account in determining the compliance with such requirement[s]. Therefore, mere reference to the deposited material in an application cannot simply replace the disclosure of such material in the application in order to comply with [the] [those] requirement[s]. 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 [the] [those] requirement[s].

107. In accordance with draft Article 5(2), the SPLT incorporates by reference Rule 13*bis* of the PCT, which provides detailed requirements concerning the reference to deposited biological material. A Contracting Party is free to determine what constitutes “a depository institution” under this provision. However, in accordance with paragraph (3), any Contracting Party shall accept the effect of a deposit made with the International Depository Authority under the Budapest Treaty.

108. Paragraph (2)(a) and (b). According to subparagraph (a), the general rule is that the deposit must be made at the latest on the filing date of the application.

[Alternative A]

However, where the disclosure of the deposited biologically reproducible material, to the extent to which it is taken into account for the purpose of draft Article 10, is compliant with draft Article 7(3), i.e., it does not add new matter to the application as of the filing date, subparagraph (b) provides for the possibility to make the deposit after the filing date. However, where a deposit is made after the filing date, the applicant would have to submit evidence that the deposited biological material and the material described in the application as filed are the same. Subparagraph (b) may be applicable to the case where, for example, the biologically reproducible material, which was not made available to the public, was used to make a claimed invention. In this case, even if the biologically reproducible material was fully and specifically identified in the description as filed and the claimed invention was clearly and completely disclosed, a physical access to the deposited biologically reproducible material may be nevertheless necessary for a third party to work on the deposited material in order to make and use the claimed invention without undue experimentation. It also covers the case where the deposit as of the filing date was made with a depository institution which was not an authorized institution for the purpose of the disclosure requirement under the applicable patent law, and therefore the applicant should re-deposit the biologically reproducible material with an authorized depository institution after the filing date.

[Alternative B]

Alternative B obliges a Contracting Party to accept a deposit after the filing date under two situations described in items (i) and (ii). Item (i) refers to the case where a third party needs to access to the sample of the material in order to make and use, without undue experimentation, the claimed invention that was made by utilizing that material, even if the material was fully and specifically disclosed in the application. In this case, the issue of adding “new matter” would not arise since the material was fully identified in the application and evidence showing that the later deposited material is identical to the material identified in the application should be required. Item (ii) refers to the case where the deposit which was made no later than the filing date was not made with a depository institution recognized in the context of the disclosure requirement under the patent law. The mere fact that the deposit was made with the depository institution that do not comply with the patent law as of the filing date is a kind of formality defect rather than substantive failure to comply with patentability requirements.

109. Paragraph (3). In order to facilitate the recognition of the effects of the deposit of biologically reproducible material contained in a patent application at the international level, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for

the Purposes of Patent Procedure (Budapest Treaty; see also draft Rule 1(1)(c)) was signed in 1977. The Budapest Treaty requires Contracting Parties to recognize a deposit with any International Depositary Authority. This paragraph obliges a Contracting Party of the SPLT to accept the effect of a deposit made with an International Depositary Authority, even if that Contracting Party is not a party to the Budapest Treaty.

Guidelines Under Article 11 and Rules 12 and 13  
(Details Concerning Claims)

110. Article 11, paragraph (1). The requirement under this paragraph is a subjective one, since the provision clarifies that it is the applicant, and not the Office, who determines what he regards as his invention and what the subject matter for which he seeks for patent protection is. Therefore, non-compliance with this requirement is not a ground for refusal of a claimed invention or for revocation or invalidation of a claim or a patent (see draft Articles 13 and 14). However, it goes without saying that, in order to obtain a patent, the claimed invention shall comply with other requirements, such as novelty, inventive-step (non-obviousness), industrial applicability (utility) and the claims shall comply with the requirements concerning the drafting of the claims.

111. Article 11, paragraph (2). The requirement that the claims shall be clear is important since, once a patent is granted, the claims define the scope of its protection. This requirement applies to individual claims as well as to the claims as a whole. Since the interpretation of the claims shall be made primarily on the basis of the wording of the claims (see draft Article 11(4)(a)), the meaning of the terms of a claim should, as far as possible, be clear for a person skilled in the art on the basis of the wording of the claim alone. The claim is deemed to be clear enough if a person skilled in the art can determine the boundaries of the claimed invention with a reasonable degree of certainty. For example, inconsistency between the terms of a claim and the description or prior art teaching, the use of terms such as “essentially,” “relatively” or “similar” in the claim, or absence of the basis of reference, where a word or a phrase refers to an earlier citation, could be considered as not complying with the clarity requirement.

112. The requirement that the claims shall be concise also applies to the individual claims as well as to the claims in their entirety. For example, undue repetition of words or a multiplicity of claims of a trivial nature which render it unduly burdensome to determine the matter for which protection is sought, could be considered as not complying with this requirement. However, it is not the intention of this provision to form a basis for allowing Offices to reduce the number of claims where there is no absence of clarity or conciseness in respect of the claims.

*Relationship of Claims to the Disclosure*

113. Article 11, paragraph (3) and Rule 12. Draft Article 11(3) provides that the description and drawings should provide a basis for the claimed invention and that the scope of the claims must not be broader than the extent of the description and drawings. In other words, the claimed invention must be fully supported by the disclosure in the description and drawings in a manner allowing a person skilled in the art to extend the teaching of such disclosure to the entire scope of the claim, thereby showing that the applicant does not claim subject matter

which he had not recognized and described on the filing date. The underlying legal principle as regards the relationship of the claims to the disclosure is that exclusive rights should be justified by the contribution to the art through the disclosure to the public of what the inventor had invented. Therefore, the protection conferred by the patent should not extend to subject matter which was not recognized and not described by the inventor as of the filing date. One example where the claims are not consistent and not commensurate with the description and drawings would be that, after reading the application, the claimed invention is still not at the disposal of a person skilled in the art, because the essential element for the function or operation of the invention is missing from the claim. 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 inventor, for example, mere speculation of possibilities that have not been explored yet.

114. 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. Therefore, in that case, non-compliance with both the requirement concerning the relationship of the claims to the disclosure under this paragraph and the enablement requirement under draft Article 10 may be invoked. However, these two requirements are distinct and separate requirements.

#### *Interpretation of Claims*

115. Article 11, paragraph (4)(a). This paragraph provides the basis for the manner of interpretation of claims for the purposes of determining compliance with the requirements in respect of the claims (see draft Article 11, paragraphs (2) and (3)), enabling disclosure (see draft Article 10), patentable subject matter (see draft Article 12(1)), novelty (see draft Article 12(2)), inventive step/non-obviousness (see draft Article 12(3)) and industrial applicability/utility (see draft Article 12(4)). Details concerning the manner of interpretation of claims are prescribed in draft Rule 13. It follows from the wording of draft Article 2(1) that draft Article 11(4) and draft Rule 13 are also applicable to the interpretation of patented claims during infringement procedures.

116. The scope of the claimed invention, i.e., the scope of the subject matter for which patent protection is sought, shall be determined on the basis of the wording of the claims. As prescribed in Rule 13, paragraph (1)(a), 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, and should not be limited in their meaning by what is explicitly disclosed in the description and drawings. Further, if the wording of the claims needs interpretation, the description and the drawings, as amended or corrected under the applicable law, and the general knowledge of a person skilled in the art on the filing date shall be taken into account. Where the description provides a special meaning by way of, for example, defining a term appearing in the claim, the description should be used for the interpretation of the claim.

117. Rule 13, paragraph (2). This subparagraph is included for avoidance of doubt. It follows from paragraph (2)(a) that the claims should not be interpreted in a limited manner by what is explicitly disclosed in the description and drawings, except where the applicant

introduces or agrees to a specific limitation (“disclaimer”). In particular, the interpretation of the claims should by no means be limited by the scope of the examples of the claimed invention contained in the description.

118. Rule 13, paragraph (4)(a). This subparagraph relates to the interpretation of a claim which defines the structure or material of a product, or the steps of a process, by their function, work or characteristics (means or step-plus-function claim). For the purposes of the interpretation of the claims, in principle, such a claim should be construed as any structure or material or act which performs the defined function or has the defined characteristics. For 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 in accordance with draft Articles 10 and 11.

119. For the purposes of determining novelty/inventive step (non-obviousness) of means or step-plus-function claims, where the defined function or character is essentially derived from a certain structure, material or act of the claimed invention, such a claimed invention would not involve novelty/inventive step (be obvious) over prior art which describes that structure, material or act as such. For example, concerning a claim such as “chemical compound X having anti-cancer effect,” where the anti-cancer effect is a characteristic which is inherent in the chemical compound X, the claim would not involve novelty/inventive step (be obvious) having regard to prior art which refers to the “chemical compound X” *per se*.

120. Rule 13, paragraph (4)(b). This subparagraph concerns a claim defining a product by its manufacturing process (product-by-process claim). Such a claim should be construed as the final 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. 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. For example, as regards a claim “protein which is obtained by process P (steps P1, P2, ... and Pn),” if protein Z manufactured by a different process Q is identical to the claimed protein, and it is part of the prior art, the claimed protein is not considered novel whether or not the process P has been publicly known as of the claim date.

121. Rule 13, paragraph (4)(c). This subparagraph concerns a claim defining a product by its particular use (product-by-use claim). Such a claim should be construed as the product being limited to the particular use. Whether the product is new or not and whether the particular use of such product is new or not having regard to the prior art are not a question of interpretation, but a question of patentability of the claimed invention. For example, a claim aimed at “a chemical compound Z for insecticidal use” may be patentable having regard to prior art which refers to the “chemical compound Z” as such, if the insecticidal use of the chemical compound Z is a new use. However, if the claim recites a new use of a composition or structure which is found in the item of prior art, and the use is directed to a result or property of that composition or structure, then the claim is anticipated by that item of prior art.

*Doctrine of Equivalents*

122. Article 11, paragraph (4)(b). The background for the inclusion of the so-called “doctrine of equivalents” was the fact that, if certain Contracting Parties were to apply the doctrine of equivalents, while others would not, applicants would be forced to draft their claims in a different manner in different countries. Details are contained in draft Rule 13(5) and (6).

123. Rule 13, paragraph (5). This provision provides that Contracting Parties shall take into account equivalent elements when interpreting claims for the purpose of the determination of infringement. In accordance with draft Article 11(1) and (4), the wording of the claim shall determine the scope of protection conferred by a patent. However, if this rule were always strictly applied, a patentee may not be able to prevent third parties from making unimportant and insubstantial changes and substitutions to the patent, which, though adding nothing substantial, are outside of the scope of the patented claim. Therefore, under certain circumstances, the scope of a patent may embrace equivalents to the claims described. On the other hand, third parties should be able to rely on the definitional and public notice function of the claims so that they could recognize the clear boundary of the scope of the patent. In this regard, the doctrine of equivalents should take account of the public’s need for clarity of patent coverage and the patentee’s need for fair protection from infringement.

124. The provision provides that the doctrine of equivalents shall be applied to individual elements of the claim, not to the equivalent of the claimed invention as a whole, since each element contained in the claim is deemed essential to define the scope of protection. As regards the timing for the determination of an “equivalent” element, if an element of the alleged infringing good meets certain conditions at the time of the alleged infringement, i.e., at the time when the act of the alleged infringement was committed, that element would be considered as being equivalent to the claimed item. It is not possible for an applicant to draft a claim that literally encompasses all the allegedly equivalent elements derived from later developed technologies that were not known to a person skilled in the art at the time of filing the patent application. However, taking into account of the technological development which had taken place between the filing date and the time of the alleged infringement, third parties may, for example, substitute a claimed element (e.g., a vacuum tube) with an equivalent element (e.g., a transistor) without any innovative effort. If the equivalents were determined on the claim date or on the date of the grant of the patent, the patentee may not be able to prevent third parties from, for example, simply replacing the claimed vacuum tube with the transistor, even if such a replacement was a general common knowledge at the time of alleged infringement.

125. Rule 13, paragraph (6). This provision provides the so-called “prosecution history estoppel” and aims at preventing applicants from extending the scope of protection of a claim to what the applicant or the patentee has explicitly excluded from the scope of the claim during prosecution. In view of the definitional and public notice functions of the claims, prosecution history should be taken into account for determining the scope of patented claims so that third parties would be able to rely on limitations made to the claimed invention during the prosecution under certain circumstances having regard to prior art. The term “any statement” includes amendments or corrections of the application or the patent.

126. The statement limiting the scope of the claims shall be taken into account only within the jurisdiction for which the statement has been made. Further, if a statement made during the prosecution of a parent application of a divisional or continuation-in-part application is relevant to the claims contained in the divisional or continuation-in-part application, such a statement may be taken into account for the purposes of determining the scope of those claims contained in the divisional or continuation-in-part application.

Guidelines Under Article 12(1) and (5) and Rule 16  
(Details Concerning Subject Matter Eligible for Protection and Exceptions)

*Subject Matter Eligible for Protection*

[Reserved]

*Exceptions*

[Reserved]

Guidelines Under Article 12(2) and Rule 14  
(Details Concerning Novelty)

127. Article 12, paragraph (2). This paragraph provides the condition of novelty. The novelty requirement is considered to be complied with where the invention does not form part of the prior art. The definition of prior art is contained in draft Article 8, draft Rules 8 and 9. Article 9 which relates to the grace period should also be taken into account. Details on an item of prior art relevant to the determination of lack of novelty are contained in draft Rule 14.

*Item of Prior Art*

128. Rule 14, paragraph (1). This paragraph contains two widely recognized principles with respect to the assessment of novelty: firstly, item (i) states that a “mosaic” approach to assessing novelty, whereby a plurality of items in the prior art are combined to defeat the novelty of an invention, may not be used. Secondly, item (ii) contains the self-evident principle according to which the primary item of prior art must enable a person skilled in the art to make and use the claimed invention, since otherwise, lack of novelty could not be justified.

129. It should be noted that the words “any item of prior art” do not mean a particular physical item, such as a book, a journal or a patent application, which contains a teaching that forms part of the prior art. Rather, they should be considered as a reference to the particular teaching itself. Therefore, in accordance with this paragraph, where a book contains more than one teaching, each teaching should be taken into account individually for the determination of lack of novelty.

130. Rule 14, paragraph (2). This paragraph deals with the questions of how, when and by whom the scope of the primary item of prior art shall be determined. The scope of the



primary item of prior art shall be determined by the explicit or inherent disclosure as of the date on which the primary item of prior art was made available to the public. The disclosure of the primary item of prior art shall be determined by a person skilled in the art on the claim date, i.e., a person skilled in the art on the claim date would determine the contents of the primary item of prior art as of the date on which the primary item of prior art was made available to the public. However, the person skilled in the art on the claim date should not interpret the contents of the primary item of prior art by using the knowledge which became available after the date on which the primary item of prior art was made available to the public (in other words, technical advancement). Further, even if a certain characteristic is not disclosed explicitly in the primary item of prior art, such characteristic is inherent, where it could be recognized by a person skilled in the art that, taking into account his/her general knowledge, the characteristic is necessarily contained in the disclosure. The critical time for the determination of the general knowledge of a person skilled in the art is the date on which the primary item of prior art was made available to the public. For example, where the primary item of prior art indicates a “vacuum tube,” even if replacing a vacuum tube with a transistor has become a part of the general knowledge of a person skilled in the art after the date on which the primary item of prior art was made available to the public, a person skilled in the art on the claim date shall determine the scope of the primary item of prior art as being limited to the “vacuum tube.” In the cases where the primary item of prior art is an earlier application under draft Article 8(2), reference is made to draft Rule 14(3).

131. Where there was a specific reference in the primary item of prior art to one or more other items of prior art, the teachings of the items of prior art which were referred to should be considered as being incorporated by reference in the primary item of prior art, if the items of prior art referred to were also available to the public on the date on which the primary item of prior art was made available to the public. The same principle applies to an item of prior art in electronic form or made available to the public in electronic means, such as hyperlinks in an Internet publication.

#### *Methodology for Assessment of Novelty*

132. For the assessment of novelty, the following steps shall be applied:

- (i) determination of the claimed invention;
- (ii) determination of a relevant item of prior art (“primary item of prior art”);
- (iii) assessment whether every and each element or step of the claimed invention is found in the scope of the primary item of prior art as prescribed in Rule 14(2).

133. An item of prior art that discloses a genus does not always anticipate a claim to a species within the genus. In other words, where a claim contains a specific disclosure, for the determination of novelty, a generic disclosure in the item of prior art does not always anticipate the claim to a specific example falling within that generic disclosure. However, where the specific example is identified with sufficient specificity in the scope of the item of prior art, the species claim is anticipated no matter how many other species are additionally described in the item of prior art.

134. On the other hand, where a claim contains generic disclosure, for the determination of novelty, the disclosure of a specific example in the item of prior art falling within a claimed generic disclosure anticipates that generic disclosure. For example, the disclosure of “copper” in the item of prior art defeats the novelty of a claim comprising “metal” as a generic concept. Similarly, where a claim defines the genus of specific species in the alternatives, for example, Markush claims (P1, P2, P3 ... Pn), the claim is anticipated if at least one of the alternatives (P1) is described in the item of prior art.

135. 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 no specific examples falling within the claimed range was disclosed, a case by case determination must be made as to the novelty of the claim. In order to anticipate the claims, the claimed subject matter should be disclosed with sufficient specificity in the item of prior art. If the claims are directed to a narrow range and the item of prior art discloses a broad range, and if the selected 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 (e.g., 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 item of prior art in order to anticipate the claims (a selection invention). The unexpected results may also render the claims unobvious.

136. In accordance with the general principle concerning the submission of evidence under Article 16, in order to determine the scope of the primary item of prior art referred to in Rule 14(2) and to ensure that the primary item of the prior art is enabling under Rule 14(1)(ii), the following evidence shall be taken into account, where appropriate:

(i) evidence which explains the meaning of terms used in the primary item of prior art;

(ii) evidence which shows that what is not disclosed in the primary item of prior art is inherent;

(iii) evidence which contributes to determine whether the primary item of prior art was enabling.

Guidelines Under Article 12(3) and Rule 15  
(Details Concerning Inventive Step/Non-Obviousness)

137. Article 12, paragraph (3). The condition of inventive step/non-obviousness is fulfilled if the invention, compared to the prior art, would not have been obvious to a person skilled in the art. The terms “having regard to the differences and similarities between the claimed invention as a whole and the prior art” point to the steps which are usually applied in practice when assessing the requirement, but also make it clear that the invention as a whole must be

inventive/non-obvious. The definition of the prior art contained in draft Article 8(2) excludes the prior art effect of earlier applications with respect to the determination of inventive step/non-obviousness. Details on the requirement of inventive step/non-obviousness are contained in draft Rule 15.

138. Rule 15, paragraph (1). Unlike for the determination of novelty, multiple items of prior art may be combined for the determination of whether the requirement of inventive step (non-obviousness) is met. As regards the words “items of prior art,” reference is made to the explanation in paragraph 129. The terms “multiple items of prior art” intend to cover the different situations where there are several teachings contained in different prior art references, for example, different published patents, or several teachings contained in the same prior art reference, such as one particular book.

139. Rule 15, paragraph (2). In determining the scope of the disclosure of the items of prior art, in addition to the explicit disclosure, an implicit disclosure, i.e., a teaching which a person skilled in the art could reasonably draw from the explicit disclosure, shall also be taken into account. The critical time for the determination of such disclosure is the claim date of the application concerned.

140. Rule 15, paragraph (3) contains the general and widely accepted principle that the general knowledge of the person skilled in the art shall be taken into account for the determination of inventive step (non-obviousness).

141. Rule 15, paragraph (4). This paragraph deals with the assessment of inventive step (non-obviousness). The combination, substitution or modification of one or more items of prior art may only lead to a lack of inventive step (non-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.

#### *Methodology for Assessment of Inventive Step/Non-Obviousness*

142. For the assessment of inventive step (non-obviousness), the following steps shall be applied:

- (i) determination of the claimed invention;
- (ii) determination 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 whether the claimed invention as a whole would have been obvious for 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.

143. In order to establish a *prima facie* case of obviousness and to determine whether there was any motivation, either in the prior art or in the general knowledge of a person skilled in the art as of the claim date, to modify, substitute or combine the teachings of the prior art, the following factors, in particular, shall be considered:

(i) relevance of the field of the art;

(ii) relevance of the problem to be solved;

(iii) relevance of the function or the characteristic of the art;

(iv) reasonable degree of predictability of the claimed invention, for example, the claimed invention does not involve an unexpected result.

144. According to Rule 2, a person skilled in the art is deemed to have the general knowledge and ordinary skills in the relevant field of the art. Common practices and experiments that normally require only the general knowledge and ordinary skills in the art are hence considered routine expedients by the person skilled in the art. Therefore, where, on the basis of the relevant items of prior art and the general knowledge, a person skilled in the art would reach the claimed invention by way of utilizing such routine expedients, the claimed invention shall be considered obvious. However, this would not apply if other evidence shows that the claimed invention does in fact involve an inventive step (is non-obvious).

145. In order to establish the positive assertion that the claimed invention involves an inventive step (non-obviousness), the following factors, in particular, shall also be taken into account as secondary considerations:

(i) whether the claimed invention fulfils 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;

(v) whether the claimed invention has a particular commercial success.

Guidelines Under Article 12(4)  
(Details Concerning Industrial Applicability/Utility)

146. Article 12, paragraph (4). This paragraph contains the condition of patentability of industrial applicability/utility. In order to reflect the debate at the SCP, three alternatives are proposed in this provision: the second and the third alternative reflect the standard contained in many national/regional legislation concerning industrial applicability and utility, respectively. The first alternative attempts to take into consideration the essence of both requirements, including real practices, and reflects a more global approach, whereby an

invention would have to be able to be made or used in any field of [commercial] activity. This alternative is intended to provide a single definition accommodating both “industrial applicability” and “utility”, since it contains the aspect of making or using the invention in any field of [commercial] activity and the aspect of exploitation, which implies a practical use of the invention. The term “commercial activity” covers any economic activity outside the sphere of a “private activity.” It should be noted, however, that, even if the word “commercial” was deleted from this paragraph, a Contracting Party would be free to allow the private use of a patented invention by third parties as an exception to the exclusive rights conferred by the patent, since the issue of the rights conferred by a patent is outside the scope of the SPLT. [Similarly, inventions concerning “methods for treatment of the human or animal body or surgery or therapy or of diagnosis practiced on the human or animal body” may be excluded from patentable inventions under applicable law of a Contracting Party.] The second sentence of Alternative B is modeled after Article 1(3) of the Paris Convention.

147. Although the requirement concerning industrial applicability/utility is closely related to other requirements such as the enabling disclosure requirement, patentable subject matter, and exceptions to the rights conferred by a patent, these requirements are distinct requirements. Further, the question concerning the technical character of an invention and the industrial applicability/utility requirement are also separate issues.

#### Guidelines Under Article 13 (Details Concerning Grounds for Refusal of a Claimed Invention)

148. Paragraph (1). This paragraph provides for the grounds on which an application shall be refused. It aims at covering all the requirements relating to the examination of an application and to the grant of a patent on a claimed invention. For that reason, the requirements of the Patent Law Treaty, which relates to formality requirements, are also covered under this provision.

149. It follows from the words “where the Office finds that” that the Office is not obliged to examine all the requirements referred to in this paragraph before the grant of a patent. If, however, the Office finds that there is any non-compliance with one or more of those requirements during the examination procedure, it should refuse the application.

150. Paragraph (2). This paragraph explicitly provides that, as far as requirements relating to the examination of an application and to the grant of a patent on a claimed invention are concerned, a Contracting Party may not refuse an application on the basis of any requirements different from or additional to those prescribed in paragraph (1). Additional consequences of the non-compliance with the requirements contained in this provision are not regulated by the Treaty or the Regulations. For example, where new matter was included in the application after the original filing date, a Contracting Party would be free to provide the possibility of according a different filing date to the relevant parts relating to the new matter.

Guidelines Under Article 14  
(Details Concerning Grounds for Invalidation or Revocation of a Claim or a Patent)

151. Paragraph (1). This paragraph provides for the grounds on which a patent, or, where applicable, a patented claim, shall be revoked or invalidated. The words “subject to the Patent Law Treaty” are included to ensure that Article 10(1) of the Patent Law Treaty continues to apply, i.e., non-compliance with one or more of the formal requirements referred to in Articles 6(1) [form or contents of application], (2) [request form], (4) [fees] and (5) [priority document] and 8(1) to (4) [form and means of transmittal of communications, language of communications, model international forms and signature of communication] of the PLT with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as the result of a fraudulent intention.

152. Similarly, this provision expressly provides that non-compliance with the requirements referred to in draft Articles 6 [unity of invention] and in the Regulations under Article 5(2)(a), namely draft Rules 4 and 5, may not be a ground for the revocation or invalidation of a patent or a claim. These requirements, although they may be needed for the processing of the application, are not essential to the patentability of the claimed invention.

153. This paragraph applies to these grounds independently of whether they are examined before the Office or before any other competent authority, including a court. The words “the invalidation or revocation” is intended to also cover sanctions which are of equivalent effect to revocation or invalidation, such as non-enforceability of rights.

154. Paragraph (2). This paragraph explicitly provides that a Contracting Party may not invalidate or revoke a patented claim or a patent on the basis of any requirements different from or additional to those prescribed in paragraph (1). Concerning the words “the invalidation or revocation,” reference is made to the explanation under paragraph (1) (see paragraph 153).

Guidelines Under Article 15  
(Details Concerning Review)

155. The term “quasi-judicial authority” aims to avoid any controversy as to whether, for example, the boards of appeal of a regional organization or an appeal body in a national Patent Office would be considered as judicial authorities.

Guidelines Under Article 16  
(Details Concerning Evidence)

156. This Article provides the general principles with respect to the submission of evidence. Under these principles, an applicant or any third party may initiate, or the Office of a Contracting Party may require, the submission of evidence supporting the veracity of any alleged fact in relation to the patentability of the claimed invention and the validity of the patented claim.

[End of document]