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INTRODUCTION

The present document contains Notes on the provisions of the draft Substantive Patent Law Treaty and the draft Regulations Under the draft Substantive Patent Law Treaty contained in documents SCP/6/2 and 3.

I. NOTES ON THE DRAFT TREATY

Notes on draft Article 1 (Abbreviated Expressions)

- 1.01 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 if, and 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 procedure, if such procedure was to be included in the Treaty, or the invalidation of a granted patent.
- 1.02 <u>Item (iv)</u>. The term "claimed invention" is proposed to be 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 Patent Cooperation Treaty (PCT) in relation to substantive matters of patentability (see for instance PCT Articles 33 to 35).
- 1.03 <u>Item (v)</u>. The term "applicant" is 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 owner for the purposes of this Treaty or the Regulations.
- 1.04 Item (vi). The term "filing date" means the actual filing date of an application, as provided for under the applicable law of a Contracting Party in accordance with Article 5 of the Patent Law Treaty (PLT). Article 5 of the PLT provides that a Contracting Party of the PLT has to accord a filing date to an application where that application complies with the three following requirements: first, an indication that the elements received on a specific date are intended to be an application for a patent for an invention must be provided (Article 5(1)(a)(i)). Second, the Office must be provided with indications which identify the applicant, and/or allow the applicant to be contacted (Article 5(1)(a)(ii) and (1)(c)). Third, the Office must have received a part which on the face of it appears to be a description (Article 5(1)(a)(iii)). No additional elements may be required for a filing date to be accorded, although the Office may accept evidence allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office, as the second element referred to above. In particular, a Contracting Party may not require one or more claims as a filing date requirement. Further, for the purpose of obtaining a filing date, an applicant could file a description in any language (Article 5(2)(b)), or replace the description and/or drawings by a reference to another application (Article 5(7)).
- 1.05 <u>Item (vii)</u>. The term "time of filing" is used in the Treaty and the Regulations only in several provisions, namely in draft Article 7(3) relating to the amendment or correction of an

application and in draft Article 8(1) concerning prior art as well as draft Rules 12(1), (3)(a) and 15(2) (in square brackets). In the case of draft Article 7(3), the specific reference to the time of filing is required in order to cover the situation where, for example, an application is filed in the morning and amended in the afternoon of the same day in a way that goes beyond the disclosure as originally filed in the morning. In this case, the applicant may withdraw the first application and file a separate application in the afternoon. In the case of draft Article 8(1), if the term "time of filing," which is included in square brackets, was included, the prior art would consist of everything which has been made available to the public before the specific time of filing, including what has been made available to the public at an earlier point in time of the same day.

1.06 <u>Item (viii)</u>. The term "priority date" is used in draft Articles 8(2) and 9, and related draft Rules, since, in the other cases, that term is covered by the term "claim date" (see Notes 1.07 to 1.09). In the case of the prior art effect of earlier applications under draft Article 8(2), however, the specific mention of the priority date is needed, since that prior art effect is based on the whole contents of the earlier application, and not on the claims alone. It is to be noted that draft Article 9 has not been discussed in depth by the SCP yet.

1.07 Item (ix). 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 claim, not to the application as a whole, and establishes the date for the determination of the patentability of the invention contained in the particular claim. Thus, different claims in an application may have different claim dates. The claim date of a claim in an application is either the actual filing date of the application containing the claim or, where a right of priority based on an earlier application has been validly claimed under the applicable law, the filing date of the earlier application containing the claim.

1.08 In order to use a consistent term to refer to the date on which the prior art is determined for each claim, it is suggested to adopt a term such as "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 (see, however, the exceptions in draft Articles 8(2) and 9, and related draft Rules, and Note 1.06). It is further to be noted that this term 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.

1.09 The second sentence of item (ix) covers the situation where several alternative limitations contained in one claim have different priority dates. The alternatives contained in square brackets reflect the different practices of Offices, some of which allow a single claim to have multiple priority dates, while others do not. In the first alternative, the claim date for

the whole claim would be the latest of the dates applicable to the different limitations, while under the second alternative, each limitation could be entitled to a different claim date.

- 1.10 Item (x). The expression "general knowledge of a person skilled in the art" as used in the Treaty and the Regulations is intended to include everything that could reasonably be expected to be known by a person skilled in the art clearly derived from his or her general knowledge, for example trivial features or information contained in basic textbooks on the subject in question, but excluding knowledge that would require inventive activity. With respect to the definition of a "person skilled in the art," reference is made to draft Rule 2 and the corresponding Notes.
- 1.11 <u>Items (xvii), (xviii) and (xx)</u> are in square brackets, since they will be needed for the final and administrative provisions, which are not included in the present provisions yet.

Note on draft Article 2 (General Principle)

2.01 This provision states, in express terms, a principle which was agreed at the fifth session of the SCP, namely that the Treaty and the Regulations do not deal with any substantive requirements related to infringement issues. The Treaty and the Regulations therefore apply to questions of patentability and validity (during both the pre-grant and post-grant stages). Consequently, the provisions relating to infringement contained in documents SCP/5/2 and 3, such as those on equivalents and on "file wrapper estoppel" are proposed to be deleted from the present draft. The Treaty and the Regulations would therefore not prevent any Contracting Party from applying any substantive requirements related to infringement, such as, for example, intervening third party rights or the determination of the scope of the claims for the purposes of infringement.

Notes on draft Article 3 (Applications and Patents to Which the Treaty Applies)

- 3.01 Paragraph (1). In principle, and subject to paragraph (2), this provision applies the Treaty and the Regulations to all 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, however, reference is made to the exceptions provided under paragraph (2) and Rule 3, and related Notes. 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.
- 3.02 <u>Item (i)</u>. The expression "applications ... which are filed ... for the Office of a Contracting Party" covers, in particular, applications for a regional patent that are filed with the Office of a State X, which is a member State of a regional organization, for onward transmission to the Office of that organization. However, 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. Accordingly, where, for example, both the

European Patent Organisation (EPO) and State X were party to the Treaty, the Treaty and the Regulations would apply to European applications and to national applications filed with the Office of State X. However, if State X were party to the Treaty, but the EPO were not, the Treaty and the Regulations would apply to national applications filed with 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 the Office of State X.

- 3.03 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" 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.
- 3.04 The scope of the Treaty and the Regulations is, unlike the PLT, not limited to those types of applications for patents for invention and for patents of addition permitted to be filed as international applications under the PCT. Thus, subject to paragraph (2), the Treaty and Regulations apply to all types of applications for patents for invention and patents of addition. The situation may therefore arise that a Contracting Party to both the PLT and the SPLT would not have to apply the Treaty and the Regulations to a certain type of application, but would have to apply the substantive requirements of the SPLT to that same application. This difference appears to be justified, since, as far as substantive requirements of patent law are concerned, there would be no apparent reason to limit the scope of the Treaty and the Regulations as is the case under the PLT, where, in order to avoid different standards as far as formalities of patent applications are concerned, the scope of the PLT was modeled after the PCT. It is to be noted that this item does not regulate the types of applications that a Contracting Party shall accept; this remains a matter for the applicable law of the Contracting Party concerned.
- 3.05 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

- item (i), although it is not obliged to do so. As regards divisional applications, reference is made to the explanation under item (ii) (see Note 3.06).
- 3.06 <u>Item (ii)</u>. This item is in square brackets, since divisional applications have been included at the specific request of the SCP. However, it may be questioned whether this item is needed in view of item (i), which seems to cover divisional applications as well. For more detailed provisions on divisional applications, reference is made to Article 4G of the Paris Convention. Nevertheless, the SCP may wish to discuss the desirability to include, in the Regulations, certain details applicable to divisional applications going beyond Article 4G of the Paris Convention.
- 3.07 Item (iii). 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 Note 3.02 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.
- 3.08 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 Note 3.03). 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.
- 3.09 <u>Paragraph (2)</u>. 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 international applications under the Patent Cooperation Treaty as long as their processing or examination has not started before national or regional Offices. One delegation further indicated at the fifth session of the SCP that one of the exceptions that may be envisaged was the so-called re-issue application.

Notes on draft Article 4 (Right to a Patent)

4.01 This provision deals with the question of who has the right to a patent. Details are contained in draft Rule 4 (see Notes R4.01 to R4.03).

- 4.02 Items (i) and (ii). 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. 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, donation, inheritance, bankruptcy and the like. In certain legal systems, the employer is considered to be the successor in title of the inventor, while in other systems, this is not the case (see Note 4.03). The specific rules in different Contracting Parties applicable to the transfer of rights as such are not affected by this provision.
- 4.03 <u>Item (iii)</u>. This item covers the situation where a person owns the right to a patent without falling under one of the categories referred to in items (i) and (ii). An example would be where the right to the patent, although the invention was made by the employee, arises originally in the person of the employer, as it is the case under certain legal systems.

Notes on draft Article 5 (Application)

- 5.01 Paragraph (1). This paragraph contains a list of the different parts an application must contain and seems to be self-explanatory. The terms "where required" in item (iv) are also used in Article 3(2) of the PCT. They are not meant to allow Offices to require drawings, but rather to allow applicants to submit such drawings where it appears necessary for the understanding of the claimed invention.
- 5.02 <u>Paragraph (2)</u>. This paragraph provides for the interface between the draft SPLT, the PLT and the PCT. Explanations are contained in document SCP/6/5 ("Study on the Interface between the SPLT, the PLT and the PCT").
- 5.03 Paragraph (3). This paragraph seems to be self-explanatory.

Notes on draft Article 6 (Unity of Invention)

- 6.01 This provision 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.
- 6.02 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 may 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.

- 6.03 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.
- 6.04 Details concerning the requirement of unity of invention are prescribed in draft Rule 7.

Notes on draft Article 7 (Amendment or Correction of Application)

- 7.01 Paragraph (1). This provision obliges the Office to provide, where it finds that any requirements provided under the Treaty and the Regulations are not complied with, at least one opportunity to subsequently remedy such non-compliance by way of, for example, an amendment or a correction. It does not regulate how and when the Office should communicate with the applicant in case of non-compliance with any requirements. 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 Notes 7.06 to 7.08). 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 Notes 13.01 to 13.03).
- 7.02 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.
- 7.03 Paragraph (2). This provision permits an applicant to subsequently remedy any non-compliance with the requirements provided under the Treaty and the Regulations on his own initiative up to the time when the application is in order for grant. For example, the Office may allow the applicant to make an amendment or correction up to the completion of the technical preparations for publication of the application. Abandoning a claim would be considered to be an amendment of the application.
- 7.04 However, where the Office provides a substantive examination, it may further limit the period during which the applicant may amend or correct the application on his own initiative. "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.

- 7.05 It is to be noted that, since this paragraph only deals with the right of the applicant to amend or correct the application, 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 this paragraph. Concerning the scope of amendments and corrections permitted, reference is made to paragraph (3) (see Notes 7.06 to 7.08).
- 7.06 Paragraph (3)(a). The consequence of the failure to comply with this requirement is provided in draft Article 13(1)(iii) (see Notes 13.01 and 13.02). The phrase "the disclosure of the invention contained in the claims, description or drawings as filed at the time of filing" includes matters that had been disclosed in the claims, description or drawings at the time of filing, but subsequently deleted from the claims, description or drawings during the prosecution of the application before the Office. 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.
- 7.07 Paragraph (3)(b). This paragraph seems to be self-explanatory.
- 7.08 <u>Paragraph (3)(c)</u>. The expression "person skilled in the art" is contained in draft Rule 2 (see Note R2.01).

Notes on draft Article 8 (Prior Art)

- 8.01 Paragraph (1). 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 this provision, first, the prior art with respect to the subject matter of a particular claim shall consist of any information which has been made available to the public anywhere in the world, before the claim date of such claim. If the words in square brackets "time of filing on the" were included, the precise time of filing of the claim on the claim date would be relevant for the determination of prior art. If these words were not included, the prior art would consist of any information that has been made available to the public before the claim date, regardless of the time of filing of that claim, but 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. Details concerning availability to the public are contained in draft Rule 8(2).
- 8.02 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 Note R8.01). 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 paragraph (2), the prior art with respect to a certain claim shall also include former applications that are filed in, or with effect for, the same Contracting Party before, but are published after, the claim date of that claim, although the contents of the former 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.

8.03 The alternatives presented within square brackets regarding the definition of "claim date" under draft Article 1(ix) result in different definitions of prior art where more than one limitation is included in one claim and those limitations are entitled to different claim dates. If the first alternative under draft Article 1(ix) was chosen, the prior art with respect to that claim would consist of any information that has been made available to the public before the latest of the different claim dates, i.e., the earliest date on which all of the alternative limitations were made available to the public. If the second alternative was included, the prior art with respect to each alternative claim limitation would be determined individually on the basis of the claim date of each limitation.

8.04 Further details concerning the availability to the public are provided in draft Rule 8 (see Notes R8.01 to R8.05).

8.05 Paragraph (2). This paragraph provides that the prior art with respect to a certain claim also consists of former applications filed in, or with effect for, the same Contracting Party, the filing date (or where applicable, the priority date) of which is earlier than the claim date of that claim, provided that the former application, or the patent granted on the former application, is published after such claim date. In accordance with draft Article 12(2) and (3), the former applications referred to in this paragraph form part of the prior art for the purpose of the determination of novelty, but not of inventive step. It is to be noted that any international application under the PCT would constitute prior art under this provision, although the Treaty and the Regulations, as a general rule, would not apply to those applications as long as they have not entered the "national phase" (see item (i) of draft Rule 3 and Note R3.01). According to Article 11(3) of the PCT, any international application accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State. Further, it should be noted that the Working Group on Reform of the PCT will re-examine the concept and operation of the designation system under the PCT.

8.06 Although the contents of a former 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 former application as of the filing date could lead to a separate patent. In addition, since the whole contents of the former application is published later, if the subject matter of the claim contained in the later application is not new having regard to the former application, that claim would not add any new contribution to the existing art.

8.07 Detailed conditions as regards the prior art effect of former applications are provided in draft Rule 9 (see Notes R9.01 to R9.07).

Notes on draft Article 9 (Information Not Affecting Patentability (Grace Period) [Alternative A] Grace Period [Alternative B])

- 9.01 This draft Article is placed in square brackets, since its inclusion may depend on discussions to be taking place at a later stage.
- 9.02 <u>Alternative A</u>. This Alternative is modeled after draft Article 12 of the Draft Treaty Supplementing the Paris Convention as Far as Patents Are Concerned ("1991 Draft"; see documents PLT/DC/3 and 69). However, the use of the words "disclosure" in the title and "disclosed" in the preamble and in item (ii)(a) of paragraph (1) have been avoided, so that the terms "disclosure" and "disclose," which appear in draft Article 10 with a different meaning, are used consistently throughout the draft SPLT.
- 9.03 <u>Alternative B</u>. This Alternative does not change the substance of Alternative A. It simply provides for the principle to be contained in the Treaty, while further details would be moved to the Regulations.

Notes on draft Article 10 (Enabling Disclosure)

- 10.01 <u>Paragraph (1)</u>. Although this provision refers to the application, since the abstract merely serves the purpose of technical information, the abstract shall not be taken into account for the determination of the sufficiency of disclosure, (see draft Article 10(2)). Where the application refers to biologically reproducible material which cannot be disclosed in the application to meet the requirements prescribed in this paragraph, the application shall be supplemented by a deposit of such material. Details concerning the deposit of biologically reproducible material are prescribed in draft Rule 11 (see Notes R11.01 and R11.02). The notion of "a person skilled in the art" is prescribed in draft Rule 2 (see Note R2.01).
- 10.02 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 may use its general knowledge to supplement the information contained in the application (see draft Rule 10(1)). 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(2). 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.

10.03 Paragraph (2). For the purposes of assessing sufficiency of disclosure, the description, claims and drawings shall be examined as submitted on the filing date, including any amendments or corrections made in accordance with draft Article 7. 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, 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 "support requirement" under draft Article 11(2), i.e., that the claims shall be fully supported by the description and the drawings, may not be met.

Notes on draft Article 11 (Claims)

- 11.01 Paragraph (1). The requirement under this paragraph is a subjective one, since it is the applicant 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).
- 11.02 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 Rule 12(1)), 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.
- 11.03 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.
- 11.04 Paragraph (3)(a). This paragraph provides that the description or 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.

- 11.05 However, non-compliance with the support requirement under this paragraph could often be considered as non-compliance with the enablement requirement under draft Article 10 as well. For example, 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, the SCP may wish to discuss the need of this subparagraph in view of draft Article 10.
- 11.06 In accordance with draft Article 14(1), once a patent has been granted, non-compliance with the requirement under this subparagraph should not be a ground for the invalidation or revocation of a claim or a patent.
- 11.07 Paragraph (3)(b). This paragraph provides that the claimed invention must be supported by the disclosure of the application as filed in a way to allow a person skilled in the art to recognize that, as of the filing date, the applicant actually was in possession of the claimed invention as his own intellectual creation.
- 11.08 Paragraph (4). 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 paragraphs (2) and (3)), enabling disclosure (see draft Article 10), patentable subject matter (see draft Article 12(1)), novelty (see draft Article 12(2)) and inventive step/non-obviousness (see draft Article 12(3)). Details concerning the manner of interpretation of claims are prescribed in draft Rule 12.

Notes on draft Article 12 (Conditions of Patentability)

- 12.01 This provision covers both eligibility as to patentable subject matter and the conditions of patentability which were, in former drafts, contained in distinct provisions. The provision is of a very important nature, since it will constitute the basis for a possible future mutual recognition of search or examination results or even patents in different Contracting Parties.
- 12.02 As regards the conditions of patentability, the provision does not provide a distinct condition of patentability with respect to either industrial applicability or utility, but requires that patentable subject matter shall include products and processes which can be made and used in any field of activity (see Note 12.04). The reasons for this are the following: although they overlap in part, there are differences between the requirements of industrial applicability used by some systems on the one hand and of utility applied by other systems, on the other hand. These differences appear to be difficult to overcome, but, in practice, only very few applications are refused on those grounds. In addition, in many cases, the condition of industrial applicability/utility can be subsumed under, or at least overlap with, other requirements, such as patentable subject matter, the definition of invention or the enabling disclosure requirement. For example, in many cases, if a claimed invention fails to demonstrate its practical application, it is probable that the application will also fail to enable a person having ordinary skills in the art to carry out the invention. Further, applications concerning certain types of inventions are refused on the basis of the definition of the term "invention" in some countries, or are considered to contain non-patentable subject matter in other countries, while in a third category of countries, applications concerning the same

inventions may be refused on the ground of lack of "industrial applicability." For example, inventions concerning "methods for treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body" are considered non-industrially applicable in some countries, while they may be excluded from patentability in the interest of public health in other countries. Further, under the law of some countries, aesthetic creations may be considered as not being applicable in "industry," while in other countries, they may not be regarded as "inventions." In addition, under many national laws, the effects of the patent right do not extend to acts of making or using patented inventions for private purposes. Therefore, even if a patent is granted to an invention which only serves for private use, that patent would not be enforceable in practice.

- 12.03 It is apparent that the notions of "industrial applicability" and "utility" are broad and, at least in part, overlap among each other as well as with other substantive requirements of patentability. In view of the objective of full harmonization of substantive patent law, it is therefore suggested not to include industrial applicability/utility as a distinct condition of patentability into the Treaty, but to deal with the issue in conjunction with patentable subject matter or any other requirement. As far as the compatibility of this suggestion with the TRIPS Agreement is concerned, it is to be noted that the TRIPS Agreement provides for minimum requirements only, and that the term "industrial applicability (utility)" used in that agreement is not further defined.
- 12.04 <u>Paragraph (1)</u>. This paragraph explicitly sets out that an invention, to be patentable, must fall within the scope of patentable subject matter, which is defined in a broad way so as to include all products and processes which can be made and used in any field of activity. It is to be noted that the terms "which can be made and used in any field of activity" are intended to cover any human activity, without being restricted to specific areas, such as "industry" or the like. In addition, these terms would allow a Contracting Party to exclude inventions from patentability which, for example, could not be made and used in any given field, or for which no use was indicated in the application. Draft Rule 13 contains a list of exceptions from patentable subject matter.
- 12.05 <u>Paragraph (2)</u>. 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, details on the requirement of novelty are contained in draft Rule 14 and in the Guideline under that draft Rule.
- 12.06 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 and the prior art" are not intended to undermine the fact that the invention as a whole must be inventive/non-obvious, but rather point to the steps which are usually applied in practice when assessing the requirement. The limitation of the prior art to the definition contained in draft Article 8(1) excludes the prior art effect of earlier applications as provided in draft Article 8(2) with respect to inventive step/non-obviousness, in conformity with the opinion of the majority of the SCP at its fifth session. Details on the requirement of inventive step/non-obviousness are contained in draft Rule 15 and in the Guideline under that draft Rule.

Notes on draft Article 13 (Grounds for Refusal of a Claimed Invention)

- 13.01 <u>Paragraph (1)</u>. 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.
- 13.02 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.
- 13.03 <u>Paragraph (2)</u>. 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).

Notes on draft Article 14 (Grounds for Invalidation or Revocation of a Claim or a Patent)

- 14.01 <u>Paragraph (1)</u>. 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 continue 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.
- 14.02 Similarly, this provision expressly provides that non-compliance with the requirements referred to in Articles 6 [unity of invention] and 11(3)(a) [support requirement] 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 issue of patentability of the claimed invention.
- 14.03 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.
- 14.04 <u>Paragraph (2)</u>. 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 Note 14.03).

Notes on draft Article 15 (Observations and Review)

- 15.01 <u>Paragraph (1)</u>. This provision parallels similar provisions under the PLT with respect to formality requirements, for example, Articles 6(7), 7(5) and 8(7). The time limit under this paragraph is prescribed in Rule 16.
- 15.02 Paragraph (2). This paragraph seems to be self-explanatory.

Note on draft Article 16 (Relationship to PLT)

16.01 This provision regulates the relationship between the present Treaty and the PLT. The difference between the two alternatives contained in square brackets are that, in the first case, which is modeled after Article 15 of the PLT and Article 15 of the Trademark Law Treaty ("TLT"), Contracting Parties would have to comply with the provisions of the PLT in the applicable law, without having to join the PLT, while, in the second case, they would have to become a party to that treaty. While the first alternative preserves the freedom of Contracting Parties to join the PLT, the second alternative would ensure the same membership in both treaties.

Note on draft Article 17 (Regulations)

17.01 No changes have been made to this provision compared to the version contained in document SCP/5/2, since it will form part of the final administrative provisions which are suggested to be discussed at a later stage. Therefore, corresponding Notes will be submitted later.

Note on draft Article 18 (Practice Guidelines)

18.01 Reference is made to Note 17.01.

II. NOTES ON THE DRAFT REGULATIONS

Note on draft Rule 1 (Abbreviated Expressions)

R1.01 This provision appears to be self-explanatory.

Note on draft Rule 2

(Person Skilled in the Art Under Articles 1(x), 7(3)(c), 10(1), 11(3)(b) and 12(3), and Rules 5(2)(b), 8(2)(b), 10(1) and (2)(iii), 11(1), 12(1) and (3)(a), 14(1)(ii) and (2) and 15)

R2.01 The person skilled in the art as defined under this provision is a kind of hypothetical person, who is supposed not only to have access to all the prior art which is available to him/her on the relevant date, but also to have understood that prior art. The reference to the "relevant date" takes into account the fact that, in certain cases, it is the actual filing date which is the relevant date, while in other cases, that date is the priority date. Some further details on the notion of "person skilled in the art" are contained in the Guideline under the present draft Rule.

Notes on draft Rule 3 (Exceptions Under Article 3(2))

R3.01 As a general rule, item (i) excepts international applications under the PCT from the scope of application of the Treaty and the Regulations, as long as the "national phase" in respect of such applications has not started. Thus, the provision under the PCT would continue to apply to international applications in the "international phase." It is proposed to include this exception in the Regulations, rather than in the Treaty, in order to maintain some flexibility with regard to possible future developments of the PCT. It is to be noted, however, that due to the introductory words "Except for Article 8(2)" in item (i), international applications under the PCT would constitute prior art under Article 8(2) even if such applications have not entered the "national phase." This exception is proposed in view of Article 11(3) of the PCT, according to which any international application accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date.

R3.02 Further exceptions provided under draft Article 3(2) are reserved at this stage.

Notes on draft Rule 4 (Details Concerning the Right to a Patent Under Article 4)

R4.01 <u>Paragraph (1)(a)</u>. 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. Although the provision does not achieve full harmonization, it follows the majority of the SCP which expressed the wish, at its fifth session, to maintain some flexibility on this issue. The

alternatives provided in draft Article 4 allow to cover the different legal regimes which may be applied under different systems.

- R4.02 <u>Paragraph (1)(b)</u>. This provision deals with the issue of applicable law for the determination of the right to a patent in the case of employee's inventions, where employer and employee are in different countries. Since it is not a provision on substantive patent law, but rather deals with the applicable law, it is placed within square brackets. It has been included in order to obtain guidance from the SCP on whether, in view of the freedom provided in subparagraph (a), such a provision might be useful for users in order to determine which law is applicable where the employer and the employee operate in different countries.
- R4.03 <u>Paragraph (2)</u>. This paragraph may contain, if the SCP so decides, the applicable rules under the Treaty concerning the right to a patent where several inventors have jointly made the invention. The corresponding text is reserved, since no request by the SCP to include such a provision has been formulated. It may further be noted that the case where several inventors have independently made the invention is not addressed under this Treaty, since it relates to a first-to-file system.

Note on draft Rule 5 (Contents and Order of Description Under Article 5)

R5.01 This Rule is placed within square brackets, since its inclusion is subject to the discussion on draft Article 5 and on document SCP/6/5. Depending on the outcome of that discussion, the text of this Rule may need to be wholly modified.

Note on draft Rule 6 (Details Concerning Claims Under Article 5)

R6.01 Reference is made to the explanation under Note R5.01.

Notes on draft Rule 7 (Details Concerning the Requirement of Unity of Invention Under Article 6)

- R7.01 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.
- R7.02 <u>Paragraph (2)</u> 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.

R7.03 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.

Notes on draft Rule 8 (Availability to the Public Under Article 8(1))

R8.01 <u>Paragraph (1)</u>. This paragraph 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, oral communication, display, use, sale or offering for sale. Information that has been made available to the public via an electronic data base 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 as well.

R8.02 Paragraph (2)(a). This paragraph 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 possibility that the information could be accessed by the public, it would also form part of the prior art. The word "reasonable" is placed within square brackets for discussion by the SCP. Without the word "reasonable," any theoretical possibility of access to the information would be sufficient for the information to qualify as prior art. For example, in an extreme case, one single copy of a book placed on the shelf of a library in a remote village may constitute prior art. On the other hand, if the word "reasonable" was retained, the level of public accessibility would be higher in a way that the availability requirement would be fulfilled only where some probability existed that, according to the concrete circumstances, the public was able to access the information.

R8.03 Paragraph (2)(b). This paragraph provides for the interpretation of the word "public" for the purposes of the definition of "prior art." It follows from the words "any person, who may not be a person skilled in the art" that the public may be one or more than one person who does not necessarily have the capability of understanding the prior art in the relevant field. However, such person (or persons) must not be bound by a confidentiality obligation, and therefore, is (are) free to disseminate the information to others, whether he (they) understand(s) the information or not.

R8.04 <u>Paragraph (3)</u>. What constitutes "corroborative evidence" is left to the applicable law of a Contracting Party. It may consist of written evidence, testimonial evidence or any other kind of evidence allowed under the law of the Contracting Party.

R8.05 <u>Paragraph (4)</u>. This provision aims at harmonizing the determination of the date of publication for the purposes of prior art, where only the year or the month, but not the date of publication, 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 is made available to the public. However, a Contracting Party would be free to consider any evidence which could determine another date as the publication date of such information.

Notes on draft Rule 9 (Prior Art Effect of Former Applications Under Article 8(2))

R9.01 Paragraph (1)(a) and (b). These provisions provide further conditions to be fulfilled for a former application to be considered as part of the prior art under draft Article 8(2). First, the "whole contents" of the former application, that is, the claims, description and any drawings of the former application (see paragraph (1)(b)), shall be considered as prior art. Since the abstract serves the purpose of technical information only, it does not form part of the prior art (see draft Article 5(3)). Second, the prior art consists of the whole contents of a former 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. Third, the former application or a patent granted on that application should be published on or after the claim date of the claim contained in the application under consideration by the competent authority. It goes without saying that, if the former application is published before the claim date, it forms part of the prior art under draft Article 8(1).

R9.02 Paragraph (1)(c). 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 as well as to divisional 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, this provision obliges that Contracting Party to consider former 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.

R9.03 Paragraph (2). This paragraph seems to be self-explanatory.

R9.04 <u>Paragraph (3)</u>. This paragraph covers the situation where the former 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 former application is still published despite its withdrawal or abandonment before the publication date. This provision therefore provides that, under these circumstances, the former application shall not be considered prior art for the purposes of draft Article 8(2). On the other hand, where the former application was withdrawn or abandoned, was considered withdrawn or abandoned, or was rejected on or after the date of its publication, that former application shall be considered as prior art, provided it was still pending before the publication date.

R9.05 Paragraph (4). This paragraph obliges a Contracting Party to provide the so-called "anti-self-collision." Therefore, although the whole contents of a former application shall be considered as prior art in accordance with draft Rule 9(1), if an applicant has claimed invention X in the former application, and the same applicant claims invention Y, which has been disclosed in the description or the drawings of the former application, in the subsequently filed application, the former 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 former application.

R9.06 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.

R9.07 Further, where the inventors named in two applications are the same, but the applicants of these applications are different, the benefit of this paragraph excluding self-collision would not be available. It follows from the phrase "one and the same person" that, where there are more than one applicant, all the applicants of the former application and the application under examination must be the same.

Notes on draft Rule 10 (Sufficiency of Disclosure Under Article 10)

R10.01 Paragraph (1). The definition of the term "general knowledge of a person skilled in the art" is prescribed in draft Article 1(x).

R10.02 <u>Paragraph (2)</u>. This paragraph 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.

R10.03 <u>Item (i)</u>. A person skilled in the art must be able to make and use the entire scope of the claimed invention without undue experimentation.

R10.04 <u>Items (ii) and (iii)</u>. The subject matter to which the claimed invention pertains is essential to determine the common knowledge of a person skilled in the art and the state of the art.

R10.05 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 references to other applications or documents. The more a person skilled in the art knows 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.

R10.06 <u>Item (vi)</u>. 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.

Notes on draft Rule 11 (Deposit of Biologically Reproducible Material Under Article 10)

R11.01 <u>Paragraph (1)</u>. The date on which biologically reproducible material has to be deposited is left to the discretion of each Contracting Party. However, harmonization is achieved as regards the earliest date which could be required for the deposit, i.e., the filing

date of the application concerned. The expression "person skilled in the art" is defined in draft Rule 2 (see Note R2.01).

R11.02 Paragraph (2). This paragraph obliges a Contracting Party to accept the effect of a deposit made with an International Depositary Authority under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty; see also Rule 1(1)(c)), even if that Contracting Party is not a party to the said Treaty.

Notes on draft Rule 12 (Interpretation of Claims Under Article 11(4))

- R12.01 Paragraph (1). As a general rule, each claim should be interpreted on the basis of the words of the claim itself. However, in certain cases, in particular, where there are doubts as to the meaning of the wording, the description, drawings and the general knowledge of a person skilled in the art shall also be taken into account.
- R12.02 Paragraph (2)(a). The words of a claim must be read as they would be interpreted by a person skilled in the art, and should not be limited in their meaning by what is explicitly disclosed in the description and drawings. However, where the description provides a special meaning by way of, for example, defining the term appearing in the claim, the description can be used for interpretation of the claim.
- R12.03 Paragraph (2)(b). This subparagraph seems to be self-explanatory.
- R12.04 Paragraph (3)(a). This subparagraph seems to be self-explanatory.
- R12.05 Paragraph (3)(b). 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. 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.
- R12.06 Paragraph (4)(a). This subparagraph relates to the interpretation of a claim which defines the structure or material of a product by its function, work or characteristics (means-plus-function claim). For the purposes of determining the novelty and inventive step (non-obviousness) of such an invention, in principle, the claimed invention should be construed as any structure or material which performs the defined function or has the defined characteristics, except in the case provided in paragraph (4)(b). 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 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 Articles 10 and 11.
- R12.07 Paragraph (4)(b). This subparagraph provides an exception with regard to the interpretation of means-plus-function claims. Where the defined function or character is

essentially derived from a certain structure or material, the claim should be construed as the structure or material 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 should be interpreted as meaning that "chemical compound X" *per se*.

R12.08 Paragraph (4)(c). 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, whatever the manufacturing process stated in the claim is, for the purposes of determining novelty and inventive step (non-obviousness). 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.

R12.09 Paragraph (4)(d). This subparagraph concerns a claim defining a product by its particular use (product-by-use claim). Such a claim should be construed as a product *per se*, unless the product is used solely for that purpose and/or is particularly suitable for such use. For example, a claim aimed at "a chemical compound Z for insecticidical use" should be construed as "a chemical compound Z," unless the characteristics of the chemical composition of compound Z shows that it is used solely for the insecticidical purpose or that it is particularly suitable for that purpose.

Notes on draft Rule 13 (Exceptions to Patentable Subject Matter Under Article 12(1))

R13.01 Following the discussions at the fifth session of the SCP, a provision on exceptions to patentable subject matter under draft Article 12(1) has been included in the Regulations. It is suggested to divide the provision into two parts: paragraph (1) would contain the subject matter which is not considered to be inventions, such as mere discoveries, abstract ideas and the like, while paragraph (2) would contain the subject matter which are considered to be inventions, but which could be excepted from patentability.

R13.02 <u>Paragraph (1), item (i)</u>. This item would exclude from patentability mere discoveries, such as things that exist as such in nature without any human intervention, natural phenomena or laws of nature without any concrete application.

R13.03 <u>Item (ii)</u>. The expression "abstract ideas as such" would encompass, in particular, mere descriptive ideas and concepts *per se*, such as for example mental activities, abstract rules or the mere presentation of information.

R13.04 <u>Item (iii)</u>. The expressions "scientific theories as such" and "mathematical methods as such" are included for the purpose of completeness, since they could, at least in part, be covered by items (i) and (ii). This item covers only the mere description of such theories and methods, but not inventions based on them.

- R13.05 <u>Item (iv)</u>. Aesthetic creations are generally not protected by patents, but by industrial designs or copyright. This item covers only the creation which has exclusively aesthetic aspects. If the creation contains any patentable element or function, those elements or functions would be patentable.
- R13.06 Paragraph (2) does not contain any proposals yet, since the SCP may wish to consider, for example, either the inclusion of Article 27.2 and 3 of the TRIPS Agreement, or a reference to those provisions into paragraph (2). It is to be noted that this paragraph is not suggested to be of a mandatory nature. This is in line with the relevant provisions of the TRIPS Agreement referred to above, which read as follows:
 - "2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
 - 3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

Notes on draft Rule 14 (Items of Prior Art Under Article 12(2))

- R14.01 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 item of prior art must enable a person skilled in the art to make and use the invention, since otherwise, lack of novelty could not be justified. It should be noted that the words "[an] item(s) 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.
- R14.02 Paragraph (2) refers to further items of prior art, which are closely linked to the primary item of prior art, such as explicit references or explanations of terms contained in the

primary item of prior art. These other items of prior art listed in items (i) to (iv) have to be taken into account for the determination of novelty together with the primary item of prior art, provided they would have been known to a person skilled in the art. With respect to item (iv), reference is made to paragraph (3) of the Guideline under draft Rule 14, which permits to take into account evidence showing that a characteristic not disclosed in the primary item of prior art was inherent on the claim date, even where that evidence has a later date than the claim date.

R14.03 Further details on the methodology for the assessment of novelty are contained in the Guideline under this draft Rule.

Notes on draft Rule 15 (Items of Prior Art Under Article 12(3))

R15.01 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 Note R14.01. The terms "multiple items of prior art may be combined,..." 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. The combination of different items of prior art may only lead to the rejection of inventive step/non-obviousness where a person skilled in the art would have been expected, with a reasonable likelihood, to combine the different items or embodiments of prior art. Conversely, where such combination could not have been expected to be done by a person skilled in the art, the requirement of inventive step/non-obviousness would be met, even if each single item was obvious if taken individually.

R15.02 <u>Paragraph (2)</u> 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.

R15.03 Further details on the methodology for the assessment of inventive step/non-obviousness are contained in the Guideline under this draft Rule.

Note on draft Rule 16 (Time Limit Under Article 15(1))

R16.01 This Rule seems to be self-explanatory.

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