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DRAFT REGULATIONS UNDER THE SUBSTANTIVE PATENT LAW TREATY

prepared by the International Bureau

TABLE OF CONTENTS

		<u>page</u>
INTRODUCT	ION	2
DRAFT REGU	ULATIONS	
Rule 1	Abbreviated Expressions	3
Rule 2	Person Skilled in the Art Under Articles 10(1), 11(4)(a) and 12(3), and Rules 7(24), 4(1)(vii), 10(iii), 11(1), 12(1)(a) and (2), 13(5)(ii), 14(1)(a) and (2) and 15(2), (3) and (4)	4
Rule 3	Exceptions Under Article 3(2)	5
Rule 4	Further Requirements Concerning Contents, Manner and Order of Description Under Article 5(21)	6
Rule 5	Further Requirements Concerning Claims Under Article $5(2\underline{1})$	9
Rule 6	Details Concerning the Requirement of Unity of Invention Under Article 6	12
Rule 7	Details Concerning Observations, Amendments or Corrections of Application Under Article 7	13
<u>Rule 7bis</u>	Clear Mistakes Under Article 7bis	16
Rule 8	Availability to the Public Under Article 8(1)	17
Rule 9	Prior Art Effect of Earlier Certain Applications Under Article 8(2)	19
Rule 10	Sufficiency of Disclosure Under Article 10	21
Rule 11	Deposit of Biological ly Reproducible Material Under for the Purposes of Article s- 10 f and 11(3)	22
Rule 12	Relationship of Details Concerning Claims to Disclosure-Under Article 11 (3)	26
Rule 13	Interpretation of Claims Under Article 11(4)	27
Rule 14	Items of Prior Art Under Article 12(2)	32
Rule 15	Items of Prior Art Under Article 12(3)	36
Rule 16	Exceptions Under Article 12(5)	37

INTRODUCTION

- 1. The present document contains a revised version of the draft Regulations Under the Substantive Patent Law Treaty (SPLT). It takes into account the views expressed in the Standing Committee on the Law of Patents at its ninth session which was held from May 12 to 16, 2003).
- 2. As regards Rules 1 to 9, differences between the former text of the draft Regulations Under the Substantive Patent Law Treaty contained in document SCP/9/3 and the revised text contained in the present document, except where an existing provision or paragraph as a whole has been moved from another provision or paragraph, have been highlighted as follows:
- (i) words which did not appear in document SCP/9/3 but appear in the present text are underlined, and
- (ii) words which appeared in document SCP/9/3 but which are omitted from the present document are shown as struck through.
- 3. As agreed by the SCP at its ninth session, provisions which the Committee has considered provisionally accepted are indicated within a frame. Such provisions are closed for further discussion, except at the express request of a Member of the Committee or to approve consequential modifications when redrafting other provisions.
- 4. Concerning Rules 10 to 16, since no discussion was held on these provisions at the ninth session of the SCP, the text of the draft Regulations under the SPLT contained in document SCP/9/3 is kept unchanged, except for some consequential changes and corrections of typographic errors, which are highlighted in grey.
- 5. It should be noted that certain of the suggested provisions (for example, draft Rule 9) reflect a first-to-file system. This approach does, however, neither prejudice the future drafting of the SPLT, nor the discussion by the Committee on the inclusion of additional issues into the Treaty.
- 6. Draft Practice Guidelines under the draft SPLT are contained in document SCP/10/6.

Rule 1

Abbreviated Expressions

- (1) [Abbreviated Expressions in the Regulations] (a) In these Regulations, the word "Treaty" means the Substantive Patent Law Treaty.
- (b) In these Regulations, the word "Article" refers to the specified Article of the Treaty.
- (c) For the purposes of these Regulations, unless expressly stated otherwise, "Budapest Treaty" means the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, signed on April 28, 1977, together with the Regulations under that Treaty, as revised and amended.
- (2) [Abbreviated Expressions Defined in the Treaty] The abbreviated expressions defined in Article 1 for the purposes of the Treaty shall have the same meaning for the purposes of these Regulations.

Rule 2

Person Skilled in the Art Under Articles 10(1), 11(4)(a) and 12(3), and Rules 4(1)(vii), 7(24), 10(iii), 11(1), 12(1)(a) and (2), 13(5)(ii), 14(1)(a) and (2) and 15(2), (3) and (4)

A person skilled in the art means a hypothetical person with general knowledge and ordinary skill in the relevant field of the art at the relevant date.

[COMMENT: In view of the discussion held at the ninth session of the SCP, this provision may be alternatively placed in the Treaty. The Practice Guidelines further elaborate the expressions "general knowledge" and "ordinary skill".]

Rule 3

Exceptions Under Article 3(2)

The applications and patents referred to in Article 3(2) are:

- (i) <u>subject to Article 1(ii)</u>, provisional applications—for patents for invention and for patents of addition;
 - (ii) applications for re-issue.

[COMMENT: The term "applications for re-issue" in item (ii) is further explained in the Practice Guidelines. Article 1(ii) and (v) clarifies that the expressions "applications" and "patents" in Article 3(1) does not cover the so-called second-tier protection.]

Rule 4

Further Requirements Concerning Contents, Manner and Order of Description Under Article 5(21)

- (1) [Contents, Manner and Order of Description] The description shall, after stating the title of the claimed invention:
- (i) specify the [technical] field or fields to which the claimed invention relates; [COMMENT: The word "technical" is placed in square brackets, pending the discussion on this issue in conjunction with draft Article 12(1). At its ninth session, the SCP agreed that the use of the term "technical" throughout the Treaty and the Regulations should best be addressed in connection with the discussion of draft Article 12(1), following which consequential changes might be considered throughout the Treaty and the Regulations.]
- (ii) indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the claimed invention, and, preferably, cite the documents reflecting such background art;
- (iii) describe the claimed invention in any terms that allow the claimed invention to be understood and, preferably, in such terms that the problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the claimed invention with reference to the background art;
- (iv) where a deposit of biologically reproducible material is required under

 Rule 11, indicate the fact that the deposit has been made and identify at least the name and

 address of the depositary institution, the date of the deposit and the accession number given to

[Rule 4(1), continued]

the deposit by that institution, as well as describe, to the extent possible, the nature and the characteristics of such material, relevant to the requirement of disclosure of the claimed invention;

[COMMENT: This purely editorial change is suggested in order to use the same terminology as in the PCT.]

- (v) briefly describe the figures in the drawings, if any;
- (vi) set forth at least one [a mode][the best mode known to the applicant at the time of filing] for carrying out the claimed invention; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any;
- (vii) indicate explicitly, where it would not otherwise be clear to a person skilled in the art from the application or nature of the claimed invention, the way or ways in which the claimed invention satisfies the requirement of being useful or industrially applicable.
- [(2) [Additional Contents] A Contracting Party may require the indication of the source and geographical origin of the deposited biological material in the description.]

[COMMENT (1): It should be noted that, where the information concerning the source or geographical origin of the deposited biological material corresponds to the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the claimed invention, such information would be required under paragraph (1)(ii). Further, where such information is essential for complying with the enabling disclosure requirement, it would be required in accordance with draft Article 10.]

[COMMENT (2): As regards the requirement concerning information about corresponding foreign applications and grants, Article 29(2) of the TRIPS Agreement does not regulate in which part of the application such information should be contained.]

(23) [Different Presentation of Contents] A Contracting Party shall accept the contents of the description presented in a manner or an order different than specified in paragraph (1) where, because of the nature of the claimed invention, a different manner or a different order would afford a better understanding or a more economical presentation of the claimed invention.

Rule 5

Further Requirements Concerning Claims Under Article 5(21)

(1) [Consecutive Numbering] Where the application contains two or more claims, they shall be numbered consecutively in whole numerals. A Contracting Party may require that a particular kind of whole numerals be used before its Office.

[COMMENT: The Practice Guidelines would clarify that the numbering of the claims would start with "1". A Contracting Party would be free to require a particular kind of numerals, such as Arabic numerals, to be used by applicants.]

- (2) [Form of Claim] Claims shall be written, at the option of the applicant, either
- [technical] features of the invention which are necessary in connection with the definition of the claimed subject matter and which, in combination, appear to be part of the prior art, the second part ("the characterizing portion"), introduced by the words "characterized in that," "characterized by," "wherein the improvement comprises" or other words to the same effect, consisting of a statement indicating those [technical] features which, in combination with the [technical] features stated in the first part, define the matter for which protection is sought; or

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At its ninth session, the SCP agreed that the use of the term "[technical]" throughout the Treaty and the Regulations should best be addressed in connection with the discussion of draft Article 12(1), following which consequential changes might be considered throughout the Treaty and the Regulations.

- (ii) in a single part containing a recitation of a combination of several [technical] feature, or a single [technical] feature, which defines the matter for which protection is sought.
- (3) [References in the Claims to the Description and Drawings] (a) No claim may, except where absolutely necessary, contain a reference to the description or any drawings, for example, such references as "as described in part ... of the description" or "as illustrated in figure ... of the drawings."
- (b) A claim may not contain drawing, but may contain tables, graphs and chemical or mathematical formulas.
- (c) Where the application contains a drawing, the mention of any [technical] feature in a claim may, if the intelligibility of that claim can thereby be enhanced, include a reference sign to the applicable part of that drawing; such a reference sign shall be placed between square brackets or parentheses.
- (4) [Dependent and Multiple Dependent Claims]² (a) Any claim which includes all the features of one or more other claims (hereinafter referred to as "dependent claim" and "multiple dependent claim," respectively) shall, preferably at the beginning, refer to the other

The text of this paragraph is subject to the outcome of the discussions in the Working Group on Multiple Invention Disclosures and Complex Applications.

[Rule 5(4)(a), continued]

claim or the other claims, as the case may be, by indicating the number of the other claim or the numbers of the other claims and shall then state those features claimed that are additional to the features claimed in the other claim or the other claims.

(b) A dependent claim and a multiple dependent claim may only refer to a preceding claim or claims.

[COMMENT: This provision is necessary, since not all the Offices of Contracting Parties might be allowed to renumber the claims ex officio under the applicable law.]

- (bc) A dependent claim may depend on another dependent claim or on a multiple dependent claim. A multiple dependent claim may depend on a dependent claim or another multiple dependent claim. A multiple dependent claim may refer in the alternative or in the cumulative to the claims on which it depends.
- (ed) All dependent claims referring back to the same claim, and all multiple dependent claims referring back to the same claims, shall be grouped together in the most practical way possible.

Rule 63

Details Concerning the Requirement of Unity of Invention Under Article 6

- (1) [Circumstances in Which the Requirement of Unity of Invention Is to Be

 Considered Fulfilled] Where a group of inventions is claimed, the requirement of unity of
 invention shall be fulfilled only when there is a [technical] relationship among those
 inventions involving one or more of the same or corresponding special [technical] features
 that define a contribution which each of those inventions, considered as a whole, makes over
 the prior art.
- (2) [Determination of Unity of Invention Not Affected by Manner of Claiming] The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether each of the inventions is claimed in a separate claim or as an alternative within a single claim.

The text of this Rule is subject to the outcome of the discussions in the Working Group on Multiple Invention Disclosures and Complex Applications. The SCP agreed at its ninth session that the discussion concerning unity of invention should be postponed.

Rule 7

Details Concerning Observations, Amendments or Corrections of Application Under Article 7

- (1) [*Time Limit Under Article 7(1)*] The time limit for making observations, amendments or corrections referred to in Article 7(1) shall be not less than [two][three] months from the date of the notification referred to in that Article.
- (2) [Exceptions Under Article 7(1)] Where the Office gave the applicant an opportunity under Article 7(1) to amend and correct the application with respect to an error or defect contained in the parent application in order to comply with any requirement under Article 13(1)⁴, but the same error or defect is nevertheless contained in the divisional, continuation or continuation-in-part application, that Office shall not be obliged to give the applicant another such opportunity under Article 7(1) in relation to that error or defect.

 [COMMENT: This paragraph is moved from former Article 7(1)(b). The revised draft clarifies the connection between Article 7(1) and this paragraph. No change in substance is intended to be introduced.]
- (3) [Amendments or Corrections on Applicant's Initiative Under Article 7(2)]

 (a) Amendments or corrections in the description, the claims and any drawings referred to in Article 7(2) may be made at least up to the time when the application is in order for grant.

 However, any Contracting Party which provides for substantive examination by its Office or through another Office may provide that, except for the correction of a clear mistake under

See the footnote under Article 13.

paragraph (4), the applicant shall have the right to make those amendments and corrections only up to the time allowed for the reply to the first substantive communication from the Office.

[COMMENT: This provision is moved from former Article 7(2). It concerns amendments and corrections in the description, claims and any drawings. Amendments and corrections in the abstract are dealt with in subparagraph (b).]

(b) A Contracting Party may provide that the right of the applicant to make amendments and corrections in the abstract referred to in Article 7(2) shall not apply where the applicant is not responsible for the preparation of the final contents of the abstract to be published.

[COMMENT: In view of the status of the abstract, i.e., mere information to the public, publishing an abstract of high quality would meet the interests of all parties concerned, including applicants. Therefore, the applicant may wish to make amendments and corrections in the abstract on his own initiative. Although Article 7(2) provides the right of applicant to make amendments and corrections in the abstract on his own initiative, the Treaty and the Regulations do not provide any time limits applicable to such amendments and corrections. They are left to the applicable law.

According to this provision, those Offices which have the authority to amend the abstract submitted by the applicant ex-officio before its publication would not be bound by Article 7(2) as far as amendments and corrections of the abstract are concerned. Further, a Contracting Party may not apply Article 7(2) in so far as abstracts are concerned to international applications, since the International Searching Authority is responsible for the preparation of the abstracts of the international applications.]

[Rule 7, continued]

(<u>24</u>) [*Clear Mistakes Under Article 7(3)*]

[Alternative A]

A mistake shall be considered clear where a person skilled in the art would have understood, as at the filing date, that the alleged mistake was clearly a mistake and that the meaning which would result from the proposed correction was clearly the same as the meaning intended in the application containing that mistake on the filing date would immediately realize that something other than what was clearly intended was written in the application. The correction shall be clear in the sense that a person skilled in the art on the filing date would immediately realize that nothing else could have been intended than what is offered as correction.

[End of Alternative A]

[COMMENT: The revised draft is inspired by a proposal to revise PCT Rule 91.1, which was submitted to the Working, Group on Reform of the PCT (see document PCT/R/WG/4/4 Add.2). It should be noted that Article 7(2) only deals with the correction of clear mistakes in the description, the claims, the abstract and any drawings.]

[Alternative B]

A mistake shall be considered clear only where a person skilled in the art on the filing date would immediately realize that nothing else could have been intended than what is offered as correction.

[End of Alternative B]

Rule 7bis

Clear Mistakes Under Article 7bis

Rule 7(4) shall apply mutatis mutandis to clear mistakes in a patent.

Rule 8

Availability to the Public Under Article 8(1)

- (1) [Form of Availability to the Public] Information made available to the public in any form, such as in written form, in electronic form, by oral communication, by display or through use, shall qualify as prior art under Article 8(1).
- (2) [Accessibility to the Public] (a) Information shall be deemed to be made available to the public, if there is a reasonable possibility that it could be accessed by the public. The reasonable possibility that information could be accessed by the public shall be considered to exist if it is possible for the public to gain access to the content of the information and to acquire possession of that content.
- (b) For the purposes of Article 8 and this Rule, the term "public" means any person who is not bound by an <u>explicit or implicit</u> obligation of confidentiality to maintain the information secret.

[COMMENT: The obligation of confidentiality does not need to be expressly stated in a confidentiality agreement. Such an obligation may also be an implicit one. In other words, the relationship between the inventor and the third party to which the invention was disclosed, should be of such a nature that a reasonable expectation existed that the information concerned should be kept secret (e.g., such as the relationship within a couple or between an employee and his/her employer).]

[Rule 8, continued]

(3) [Determination of the Date of Availability to the Public] Where information allows the determination of only the month or the year, but not the specific date of availability to the public, the information shall be presumed to have been made available to the public on the [first][last] day of that month or that year, respectively, unless any evidence proves otherwise.

[COMMENT: The Practice Guidelines further elaborate the issues in relation to the alternative words "first" and "last".]

Rule 9

*Prior Art Effect of Earlier*Certain Applications Under Article 8(2)

- (1) [Principle of "Whole Contents"] (a) The whole contents of an earlier another application referred to in Article 8(2) shall consist of the description, claims and drawings as of the filing date.
- (b) The <u>earlier-other</u> application referred to in subparagraph (a) may be an application for the grant of a patent or an application for a utility model or any other title protecting an invention under the applicable law, provided that the applicable law allows for only one of those titles to be validly granted with effect for a Contracting Party for the same claimed invention.
- (2) [Applications No Longer Pending] Where the earlier_other_application referred to in Article 8(2) has been published made available to the public in accordance with Article 8(2) in spite of the fact that, before the date of its publication which the application was made available to the public, it [was no longer pending and should not have been published made available to the public under the applicable law][had been withdrawn], it shall not be considered as prior art for the purposes of that Article 8(2).

[COMMENT: The words "no longer pending" mean that, for example, the application had lapsed, was withdrawn or abandoned, considered withdrawn or abandoned, or was refused or rejected.]

[(3) [Anti-Self-Collision] Article 8(2) and paragraphs (1) to (3)and (2) shall not apply when the applicant in respect of, or the inventor identified in, the earlier other application and the applicant in respect of, or the inventor identified in, the application under examination, are, at the filing date of the application under examination, one and the same person, provided that only one patent may be validly granted with effect for a Contracting Party for the same claimed invention.]

[COMMENT: Shortly after filing an earlier application that disclosed invention X in the description, but not in the claims, the applicant may realize that his invention X is worth seeking for patent protection. This may happen, in particular in the first-to-file environment, since applicants are keen on filing applications as early as possible. In this case, without an anti-self collision provision, even if the applicant files another later application claiming invention X before the publication of his earlier application, his later application would be refused, since the whole contents of his earlier application form part of the prior art. In those countries which allow internal priority, this may not be a problem, because the applicant could simply claim the inetrnal priority of earlier application. The effect is, however, not the same, since in the case of internal priority, the applicant should file a subsquent application within one year from the filing date of the earlier application, while the introduction of the anti-self collision would allow him to file a subsquent application by the time of publication, which is normally longer than the priority period.]

Rule 10

Sufficiency of Disclosure Under Article 10

When assessing absence of undue experimentation under Article 10(1), the factors to be considered shall include:

	(i)	the breadth of the claims;
	(ii)	the nature of the claimed invention;
	(iii)	the general knowledge of a person skilled in the art;
	(iv)	the level of predictability in the art;
prior art;	(v)	the amount of direction provided in the application, including references to
	(vi)	the amount of experimentation required to make or use the claimed
invention	on the	basis of the disclosure.

Rule 11

Deposit of Biologically Reproducible Material Under for the Purposes of Articlefs 10 f and 11(3)

- (1) [Deposit of Biologically Reproducible Material] Where:
 - (i) thean application refers to biologically reproducible material which is not available to the public; and
 - (ii) that material cannot be disclosed described in the application in such a way as to enable a person skilled in the art to carry out the claimed invention without having access to that material, as required by to comply with Article[s] 10, or to describe the claimed invention in compliance with Article [and 11(3) without a person skilled in the art having access to that material;] and such material is not available to the public,

the applicant may, to the extent that the material cannot be described in the application as set forth in item (ii), remedy the non-compliance with these Articles by depositing the material shall be deposited with a depositary institution in accordance with Article 5(2)the applicable law. In this case, to the extent that the requirements under Article[s] 10 [and 11(3)] cannot otherwise be complied with, the deposit shall be considered part of the description.

[COMMENT: The revised draft is intended to clarify the circumstances under which a deposit of biologically reproducible material is required.]

[Rule 11, continued]

(2) [Time of Deposit]

[Alternative A]

(a) Subject to subparagraph (b), $t\underline{T}$ he deposit shall be made no later than the filing date of the application.

(b) Where the disclosure of the deposited biologically reproducible material, to the extent to which it is taken into account for the purpose[s] of Article[s] 10 [and 11(3)], is compliant with Article 7(3), a Contracting Party [may] [shall] accept a deposit which was made after the filing date of the application, provided the applicant submits proof that the deposited biologically reproducible material is the biologically reproducible material specifically identified in the application as filed.

[End of Alternative A]

[Alternative B]

- (a) Subject to subparagraph (b), the deposit shall be made no later than the filing date of the application.
- (b) A Contracting Party shall accept a deposit which was made after the filing date of the application, but during the pendency of the application, if:

- (i) access to the deposited biologically reproducible material by a third party is necessary for compliance with Article[s] 10 [or 11(3)], even if the deposited material was fully and specifically identified in the application on the filing date; or
- (ii) the deposit was made on or before the filing date of the application with a depositary institution which does not comply with the applicable law, and the applicant should re-deposit the deposited material with a depositary institution which complies with the applicable law,

provided the applicant submits evidence that the deposited biologically reproducible material is the biologically reproducible material specifically identified in the application as filed.

[End of Alternative B]

[COMMENT: Alternative B is intended to provide harmonized rules at the international level that allow a deposit after the filing date under limited circumstances. Draft item (i) of Alternative B refers to the case where, for example, biologically reproducible material, which was not available to the public, was used to make a claimed invention so that, despite full and specific identification of that material in the description, third parties need access to that material in order to make and use the claimed invention without undue experimentation.]

[Rule 11, continued]

(3) [International Depositary Authority] No-A Contracting Party shall refuse the effect of a deposit referred to in paragraph (1) if it has been made with an recognize any International Depositary Authority under the Budapest Treaty as a competent depositary institution for the purposes of paragraph (1).

Rule 12

Relationship of Details Concerning Claims to Disclosure Under Article 11(3)

- (1) [Clear and Concise Claims] (a) The claims shall be considered to be clear if a person skilled in the art can determine the boundaries of the claimed invention with a reasonable degree of certainty.
- (b) The claims shall be considered to be concise if they do not contain undue repetition or a multiplicity of claims of a trivial nature which render it unduly burdensome to determine the subject matter for which protection is sought.

[COMMENT: Following the discussion at the eighth session of the SCP, these provisions are moved from the Practice Guidelines.]

(2) [Relationship of Claims to Disclosure] The subject matter of each claim shall be supported by the [claims,] description and drawings in such a manner as to allow a person skilled in the art to extend the teaching therein 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.

[COMMENT: As regards the word "claims" in square brackets, see the comment under draft Article 11(3).]

Rule 13

Interpretation of Claims Under Article 11(4)

(1) [Literal Wording of the Claims] (a) The words used in the claims shall be interpreted in accordance with the meaning and scope which they normally have in the relevant art, unless the description provides a special meaning.

[COMMENT: At its eighth session held from May 5 to 9, 2003, the Meeting of International Authorities Under the PCT (MIA) agreed that the same issue should be addressed in the draft Revised PCT International Search and Preliminary Examination Guidelines as follows: "The words used in the claims shall be interpreted in accordance with the ordinary meaning and scope which would be attributed to them by a person skilled in the art, unless the description provides a special meaning."]

- (b) The claims shall not be interpreted as being necessarily confined to their strict literal wording.
- (2) [No Limitation to Express Disclosure] (a) The claims shall not be limited to the embodiments expressly disclosed in the application, unless the claims are expressly limited to such embodiments.
- (b) If the application contains examples of the embodiments of the claimed invention or examples of the functions or results of the claimed invention, the claims shall not be interpreted as limited to those examples, unless the applicant states that they shall be so limited; in particular, the mere fact that a claimed invention includes unless expressly so stated by the applicant, an example shall not eliminate from the scope of a claimed invention

<u>any</u> additional features <u>not found in the examples disclosed in the application or patent, lacks</u>

features found in such examples or does not achieve every <u>or</u> objective or <u>possess every</u>

advantage <u>not</u> cited or inherent in <u>such the</u> examples <u>shall not remove that claimed invention</u>

from the scope of the claims.

[COMMENT: The suggested modification is intended to simplify and clarify the provision.]

- (3) [Reference Signs] Any reference signs to the applicable part of the drawing referred to in Rule 5(43)(c) shall not be construed as limiting the claims.
- (4) [Special Types of Claims] (a) Where a limitation in the a claim defines a means or a step in terms of its function or characteristics without specifying the structure or material or act in support thereof, such a limitation that claim shall be construed as defining any structure or material or act which is capable of performing the same function or which has the same characteristics.

[COMMENT: For the purpose of the interpretation of claims, subparagraph (a) shall apply to means (step)-plus-function claims. For the purpose of determining novelty/inventive step (non-obviousness) of the means (step)-plus-function claim, where the defined function 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.]

(b) Where a limitation in the a claim defines a product by its manufacturing process, such a limitation that claim shall be construed as defining the product *per se* having the characteristics imparted by the manufacturing process.

[Rule 13(4), continued]

(c) Where a limitation in the a claim defines a product for a particular use such a limitation that claim shall be construed as defining the product being limited to such use only.

[COMMENT: For the purpose of the interpretation of product-by-use claims, such claims should be construed as the product being limited to the particular use. Therefore, if a claim defines a product for a particular use, the scope of the claim shall be limited to the product for such 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 is not a question of interpretation, but a question of patentability of the claimed invention. It should be noted that this provision concerns a product claim limited to a particular use (ex. a chemical compound Z for insecticidical use), and not a use claim (ex. use of compound X as a herbicide).]

(5) [Equivalents]

[Alternative A]

For the purposes of Article 11(4)(b), an element ("the equivalent element") shall generally be considered as being equivalent to an element as expressed in a claim ("the claimed element") if, at the option of a Contracting Party:

- (i) it performs substantially the same function in substantially the same way and produces substantially the same result as the claimed element; or
- (ii) it is obvious to a person skilled in the art that substantially the same result as

 that achieved by means of the claimed element can be achieved by means of the

 equivalent element;

[Rule 13(5), continued]

at the time of the alleged infringement.

[End of Alternative A]

[Alternative B]

For the purposes of Article 11(4)(b), an element ("the equivalent element") shall generally be considered as being equivalent to an element as expressed in a claim ("the claimed element") if, at the time of an alleged infringement:

- (i) the difference between the claimed element and the equivalent element is not substantial and the equivalent element produces substantially the same result as the claimed element; and
- (ii) a person skilled in the art had no reason to assume that the equivalent element had been excluded from the claimed invention.

[COMMENT: As regards item (i), the Practice Guidelines clarify that, whether the difference between the claimed element and the equivalent element is substantial or not should be determined taking into account, for example, the following factors: (a) the function of the claimed element and the equivalent element; (b) the way the claimed element and the equivalent element perform; and (c) whether the substitution is predictable to a person skilled in the art. In order to determine the applicability of item (ii), the Practice Guidelines provide that (a) prior art and (b) prosecution history (estoppel based on acts and statements made to obtain and maintain a patent) may be taken into account.]

[End of Alternative B]

[Rule 13, continued]

(6) [*Prior Statements*] In determining the scope of protection conferred by the patent, due account [shall][may] be taken of any statement limiting the scope of the claims made by the applicant or the patentee during procedures concerning the grant or the validity of the patent in the jurisdiction for which the statement has been made.

Rule 14

Items of Prior Art Under Article 12(2)

- (1) [*Primary Item of Prior Art*] (a) An item shall qualify as an item of prior art only if it enables a person skilled in the art to make and use the claimed invention.
- ("primary item of prior art") (i) may only be taken into account individually and may not be combined with other items of prior art, and (ii) shall enable a person skilled in the art to make and use the claimed invention.

[COMMENT: The second part of the sentence provides the principle that the item of prior art relevant to the determination of lack of novelty shall be enabling. The words "make and use" are in line with draft Article 10(1). The questions as to how, when and by whom the scope of the primary item of prior art shall be determined are dealt with in paragraph (2).]

(c) An item of prior art incorporated by explicit reference in another item of prior art shall be considered to form part of the latter item of prior art.

[COMMENT: This subparagraph has been moved from former paragraph (2)(b).]

(2) [Scope of the Primary Item of Prior Art] (a)

[Alternative A]

The scope of the primary item of prior art shall be determined by what was explicitly or inherently disclosed on the date on which the primary item of prior art was made available to the public to a person skilled in the art as of that date. The extent of disclosure of the primary

[Rule 14(2), continued]

that the knowledge which became available to the person skilled in the art after the date on which the primary item of prior art was made available to the public shall be disregarded for the purposes of the determination of the scope of the primary item of prior art.

- (b) Items of prior art which are incorporated by explicit reference in the primary item of prior art shall be considered to form part of the primary item of prior art.

 [COMMENT: This subparagraph has been moved to paragraph (1)(b).]
- (3) [Earlier-Other Application as Primary Item of Prior Art] Where the primary item of prior art is an earlier another application referred to in Article 8(2), the reference to the date on which the primary item of prior art was made available to the public in paragraph (2) shall be considered as a reference to the filing date of the earlier-other application or, where applicable under Article 8(2)(b), the filing date of the previous application.

[End of Alternative A]

[COMMENT: According to Alternative A, the scope of the item of prior art is determined by a person skilled in the art as of the date on which that item was made available to the public. That is, the subject matter which had been disclosed, both explicitly and inherently, on the date on which the item of prior art became available to the public, should be determined by a person skilled in the art as of the disclosure date of the item of prior art. It could be argued that, since this provision concerns the determination of novelty, the person skilled in the art who determines the subject matter which had been disclosed on the date on which the item of prior art became available to the public should be the person skilled in the art as of the priority date of the claimed invention.]

[Alternative B]

The scope of the primary item of prior art shall be determined by what was explicitly or inherently disclosed on the date on which the primary item of prior art was made available to the public to a person skilled in the art as of the priority date of the claimed invention. The extent of disclosure of the primary item of prior art shall be determined by a person skilled in the art on the claim date, provided that the knowledge which became available to the person skilled in the art after the date on which the primary item of prior art was made available to the public shall be disregarded for the purposes of the determination of the scope of the primary item of prior art.

- (b) Items of prior art which are incorporated by explicit reference in the primary item of prior art shall be considered to form part of the primary item of prior art.

 [COMMENT: This subparagraph has been moved to paragraph (1)(b).]
- (3) [Earlier Application as Primary Item of Prior Art] Where the primary item of prior art is an earlier application referred to in Article 8(2), the reference to the date on which the primary item of prior art was made available to the public in paragraph (2) shall be considered as a reference to the filing date of the earlier application or, where applicable under Article 8(2)(b), the filing date of the previous application.

[End of Alternative B]

[Rule 14(3), continued]

[COMMENT (1): Alternative B provides that what had been disclosed, both explicitly and inherently, in the item of prior art is determined by the person skilled in the art as of the priority date of the claimed invention under examination. Consequently, this person skilled in the art would utilize his knowledge as of the priority date of a claimed invention in order to determine the subject matter which was disclosed explicitly or implicitly in the item of prior art.]

[COMMENT (2): It should be noted that, where the item of prior art is a part of prior art referred to in draft Article 8(1), the difference between Alternative A and B may not be material for the purpose of the determination of the patentability of the claimed invention concerned. For example, under Alternative A, if the claimed invention is obvious to a person skilled in the art on the basis of the disclosure in the item of prior art and the knowledge which has been acquired by a person skilled in the art as of the priority date of the claimed invention, the claimed invention would not involve an inventive step (even if it is novel). However, where the item of prior art is part of the prior art referred to in Article 8(2), in certain cases, there could be a substantial difference between the two alternatives when determining the patentability of the claimed invention.]

Rule 15

Items of Prior Art Under Article 12(3)

- (1) [*Items of Prior Art*] The prior art referred to in Article 12(3) may consist of a single item of prior art or of multiple items of prior art.
- (2) [Scope of the Items of Prior Art] The scope of the items of prior art referred to in paragraph (1) shall be determined by what is explicitly or implicitly inherently disclosed, to a person skilled in the art, as of the claim date priority date of the claimed invention.
- (3) [General Knowledge of the Person Skilled in the Art] For the determination of inventive step (non-obviousness), the general knowledge of the person skilled in the art on the claim date priority date of the claimed invention shall be taken into account.
- (4) [Obviousness of the Claimed Invention] A claimed invention as a whole shall be considered obvious under Article 12(3), if any item or items of prior art or the general knowledge of a person skilled in the art would have [motivated] [prompted] a person skilled in the art, on the claimed date of the claimed invention, to reach the claimed invention by substituting, combining or modifying one or more of those items of prior art.

[COMMENT: The term "motivated/<u>prompted</u>" is intended to clarify that the mere fact that a person skilled in the art arrived at the claimed invention may not be sufficient to refuse the inventive step, but that the prior art should trigger a process to arrive at the claimed invention.]

SCP/10/3
page 37

*Rule 16*⁵

Exceptions Under Article 12(5)

Contracting	Parties	may	exclude	from	patentability	7:
					I	

[Reserved]⁶

[End of document]

The SCP agreed at its eighth session to postpone the discussion on this Rule.

The SCP may consider the inclusion of the substance of Articles 27.2 and 3 of the TRIPS Agreement or a reference to these provisions.