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DRAFT REGULATIONS UNDER
THE SUBSTANTIVE PATENT LAW TREATY
[CLEAN TEXT]

prepared by the International Bureau

TABLE OF CONTENTS

	<u>page</u>
INTRODUCTION	2
DRAFT REGULATIONS	
<i>Rule 1</i> <i>Abbreviated Expressions</i>	3
<i>Rule 2</i> <i>Person Skilled in the Art Under Articles 10(1), 11(4)(a)</i> <i>and 12(3), and Rules 7(4), 4(1)(vii), 10(iii), 11(1), 12(1)(a) and (2),</i> <i>13(5)(ii), 14(1)(a) and (2) and 15(2), (3) and (4)</i>	4
<i>Rule 3</i> <i>Exceptions Under Article 3(2)</i>	5
<i>Rule 4</i> <i>Further Requirements Concerning Contents, Manner and Order of</i> <i>Description Under Article 5(1)</i>	6
<i>Rule 5</i> <i>Further Requirements Concerning Claims Under Article 5(1)</i>	8
<i>Rule 6</i> <i>Details Concerning the Requirement of Unity of Invention</i> <i>Under Article 6</i>	11
<i>Rule 7</i> <i>Details Concerning Observations, Amendments</i> <i>or Corrections of Application Under Article 7</i>	12
<i>Rule 7bis</i> <i>Clear Mistakes Under Article 7bis</i>	14
<i>Rule 8</i> <i>Availability to the Public Under Article 8(1)</i>	15
<i>Rule 9</i> <i>Prior Art Effect of Certain Applications Under Article 8(2)</i>	16
<i>Rule 10</i> <i>Sufficiency of Disclosure Under Article 10</i>	18
<i>Rule 11</i> <i>Deposit of Biological Material for the Purposes of</i> <i>Articles 10 and 11(3)</i>	19
<i>Rule 12</i> <i>Details Concerning Claims Under Article 11</i>	22
<i>Rule 13</i> <i>Interpretation of Claims Under Article 11(4)</i>	23
<i>Rule 14</i> <i>Items of Prior Art Under Article 12(2)</i>	26
<i>Rule 15</i> <i>Items of Prior Art Under Article 12(3)</i>	28
<i>Rule 16</i> <i>Exceptions Under Article 12(5)</i>	29

INTRODUCTION

The present document is a clean version of the draft Regulations under the Substantive Patent Law Treaty (SPLT) as contained in document SCP/10/3. All underlinings, strike-throughs and comments have been removed from the text in order to facilitate the reading of the text.

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(4), 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.

Rule 3

Exceptions Under Article 3(2)

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

- (i) subject to Article 1(ii), provisional applications;

- (ii) applications for re-issue.

Rule 4

*Further Requirements Concerning Contents, Manner and Order of Description
Under Article 5(1)*

(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;

(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 biological 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 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;

[Rule 4(1), continued]

(v) briefly describe the figures in the drawings, if any;

(vi) set forth [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.]

(3) *[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(1)

(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.

(2) [*Form of Claim*] Claims shall be written, at the option of the applicant, either

(i) in two parts, the first part consisting of a statement indicating those [technical]¹ 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

(ii) in a single part containing a recitation of a combination of several [technical] features, or a single [technical] feature, which defines the matter for which protection is sought.

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.

[Rule 5, continued]

(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*] (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 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.

(c) 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.

(d) 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 6²

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.

² 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)³, 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.

(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 paragraph (4), the applicant shall have the right to make those amendments and corrections

³ See the footnote under Article 13.

[Rule 7(3)(a), continued]

only up to the time allowed for the reply to the first substantive communication from the Office.

(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.

(4) [*Clear Mistakes*] 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.

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 explicit or implicit obligation of confidentiality to maintain the information secret.

(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.

Rule 9

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

(1) [*Principle of “Whole Contents”*] (a) The whole contents of another application referred to in Article 8(2) shall consist of the description, claims and drawings as of the filing date.

(b) The other 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 other application has been made available to the public in accordance with Article 8(2) in spite of the fact that, before the date on which the application was made available to the public, it [was no longer pending and should not have been made available to the public under the applicable law][had been withdrawn], it shall not be considered as prior art for the purposes of Article 8(2).

(3) [*Anti-Self-Collision*] Article 8(2) and paragraphs (1) and (2) shall not apply when the applicant in respect of, or the inventor identified in, the other application and the applicant in respect of, or the inventor identified in, the application under examination, are, at the filing

[Rule 9(3), continued]

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.]

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;
- (v) the amount of direction provided in the application, including references to prior art;
- (vi) the amount of experimentation required to make or use the claimed invention on the basis of the disclosure.

Rule 11

Deposit of Biological Material for the Purposes of Articles 10 and 11(3)

(1) [*Deposit of Biological Material*] Where:

- (i) an application refers to biological material which is not available to the public; and
- (ii) that material cannot be 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 Article 10, or to describe the claimed invention in compliance with Article 11(3) without a person skilled in the art having access to that material;

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 with a depositary institution in accordance with the applicable law.

(2) [*Time of Deposit*]

[Alternative A]

The deposit shall be made no later than the filing date of the application.

[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 biological material by a third party is necessary for compliance with Articles 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 biological material is the biological material specifically identified in the application as filed.

[End of Alternative B]

[Rule 11, continued]

(3) [*International Depository Authority*] A Contracting Party shall recognize any International Depository Authority under the Budapest Treaty as a competent depository institution for the purposes of paragraph (1).

Rule 12

Details Concerning Claims Under Article 11

(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.

(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.

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.

(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, unless expressly so stated by the applicant, an example shall not eliminate from the scope of a claimed invention any additional features or objective or advantage not cited or inherent in the example.

(3) [*Reference Signs*] Any reference signs to the applicable part of the drawing referred to in Rule 5(3)(c) shall not be construed as limiting the claims.

(4) [*Special Types of Claims*] (a) Where 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, 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.

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

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

(5) [*Equivalents*] 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.

[Rule 13, continued]

(6) [*Prior Statements*] In determining the scope of protection conferred by the patent, due account [shall][may] be taken of a 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) [*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.

(b) Any item of prior art relevant to the determination of lack of novelty may only be taken into account individually and may not be combined with other items of prior art.

(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.

(2) [*Scope of the Item of Prior Art*]

[Alternative A]

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

(3) [*Other Application as Item of Prior Art*] Where the item of prior art is 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

[Rule 14(3), continued]

to the filing date of the other application or, where applicable under Article 8(2)(b), the filing date of the previous application.

[End of Alternative A]

[Alternative B]

The scope of the item of prior art shall be determined by what was explicitly or inherently disclosed to a person skilled in the art as of the priority date of the claimed invention.

[End of Alternative B]

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 inherently disclosed, to a person skilled in the art, as of the 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 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 priority date of the claimed invention, to reach the claimed invention by substituting, combining or modifying one or more of those items of prior art.

Rule 16⁴

Exceptions Under Article 12(5)

Contracting Parties may exclude from patentability:

[Reserved]⁵

[End of document]

⁴ The SCP agreed at its eighth session to postpone the discussion on this Rule.

⁵ 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.