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DRAFT REGULATIONS UNDER
THE SUBSTANTIVE PATENT LAW TREATY

prepared by the International Bureau

TABLE OF CONTENTS

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 <u>1(xi)</u>, 7(3)(b), 10(1), 11(3)(b) and (4)(a) and 12(3), and Rules 1(e)(i), 4(1)(vii) and (2)(b), 10(iii), <u>11(1)</u>, 12(5), <u>13(5)(ii)</u>, 14(1)(ii), <u>and (2)(a)</u> and (b) and 15(2), (3) and (4)</i>	5
<i>Rule 3</i> <i>Exceptions Under Article 3(2)</i>	6
<i>Rule 4</i> <i>Further Requirements Concerning Contents and Order of Description Under Article 5(2)</i>	7
<i>Rule 5</i> <i>Further Requirements Concerning Claims Under Article 5(2)</i>	10
<i>Rule 6</i> <i>Details Concerning the Requirement of Unity of Invention Under Article 6</i>	13
<i>Rule 7</i> <i>Time Limit Under Article 7(1)</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 Earlier 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 Biologically Reproducible Material Under Article <u>[s]</u> 10 <u>[and 11(3)]</u></i>	19
<i>Rule 11bis<u>12</u></i> <i>Relationship of Claims to Disclosure Under Article 11(3)</i>	22
<i>Rule 12<u>3</u></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>	28
<i>Rule 15</i> <i>Items of Prior Art Under Article 12(3)</i>	30
<i>Rule 13<u>6</u></i> <i>Exceptions Under Article 12(5)</i>	31

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 seventh session (May 6 to 10, 2002).

2. Differences between the former text of the draft Regulations Under the Substantive Patent Law Treaty contained in document SCP/7/4 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/7/4 but appear in the present text are underlined, and

(ii) words which appeared in document SCP/7/4 but which are omitted from the present document are shown as struck through.

3. 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.

4. Draft Practice Guidelines under the draft SPLT are contained in document SCP/8/4.

DRAFT REGULATIONS

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,
- (i) “features of the invention” mean the features that characterize the claimed invention as a whole;
- (ii) “limitation” means the elements or steps which are used to describe the claimed invention;
- (iii) “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.

[Rule 1, continued]

(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 1(xi), 7(3)(b), 10(1), ~~11(3)(b) and (4)(a)~~ and 12(3), and Rules ~~1(e)(i)~~, 4(1)(vii) ~~and (2)(b)~~, 10(iii), 11(1), ~~12(5)~~, 13(5)(ii), 14(1)(ii), and (2)(a) and (b) and 15(2), (3) and (4)

A person skilled in the art shall be considered to be a hypothetical person deemed to ~~have access to and to understand all prior art under Article 8, and to have ordinary skills and general knowledge and ordinary skill,~~ in the relevant field of the art at the relevant date, ~~as prescribed in the Practice Guidelines.~~

[*COMMENT: The modifications reflect the discussion at the seventh session of the SCP (see paragraph 67 of document SCP/7/8 Prov.2.)*]

Rule 3

Exceptions Under Article 3(2)

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

(i) ~~[except for Article 8(2),] international applications, for patents for invention and for patents of addition, under the Patent Cooperation Treaty the processing or examination of which has not started under Article 23 or 40 of that Treaty; provisional applications for patents for invention and for patents of addition;~~

(ii) [Reserved]

[COMMENT: One delegation further indicated at the sixth session of the SCP that further exceptions that may be envisaged were applications in the context of the so-called re-issue and re-examination proceedings.]

Rule 4

*Further Requirements Concerning Contents and Order of Description
Under Article 5(2)*

(1) [*Contents 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, as it relates to the provision concerning patentable subject matter in draft Article 12(1). However, even if a claimed invention is a product or process in a given field of technology, in some cases, the claimed invention can be better understood by way of referring to a non-technical field to which it relates, for example, electronic purchasing, the generation of pages for an Internet web site or the management of financial capital.]

(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;

[COMMENT: The deletion of the word “preferably” within square brackets would have the effect that an applicant would be obliged to cite the background art documents in the description, if they are known to him/her. It would not require the citation of all the prior art documents known to the applicant, but would oblige the applicant to cite the documents reflecting the background art which could be useful for the understanding and examination of the claimed invention only where these documents are known to the applicant. This would contribute to the access to the background art by third parties as well as by examiners of patent Offices dealing with substantive examination, and achieve a higher degree of harmonization.]

[Rule 4(1), continued]

(iii) describe the claimed invention, ~~as claimed, in such 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 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;

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

(vi) set forth at least one mode 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, ~~when it is~~ 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) [*Manner and Order of Presentation of Contents*] ~~(a)~~ 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.

~~(b) Any Contracting Party may accept a description which contains, in lieu of the matter specified in paragraph (1)(iii), a description of the claimed invention in any terms that allow the claimed invention to be understood.~~

Rule 5

Further Requirements Concerning Claims Under Article 5(2)

(1) [*Consecutive Numbering*] Where the application contains ~~several~~ two or more claims, they shall be numbered consecutively in whole numerals.

(2) [*Method of Definition of Invention*] The definition of the matter for which protection is sought shall be in terms of the ~~technical~~ features of the invention, which shall be expressed in the form of one or more limitations.

[*COMMENT: At its seventh session, the SCP agreed that the word “technical” be deleted in the present paragraph (see paragraph 52 of document SCP/7/8 Prov.2).*]

(3) [*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~~ features limitations 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 features which, in combination with the ~~features~~ limitations 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 limitations, or a single limitation, which defines the matter for which protection is sought.

[COMMENT: At its seventh session, the SCP agreed that the word “technical” be deleted from the present paragraph (see paragraph 52 of document SCP/7/8 Prov.2).]

(4) *[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) No claim may contain any drawing. ~~Any~~ claim may contain tables, graphs and chemical or mathematical formulas.

(c) Where the application contains a drawing, the mention of any limitation 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.

[Rule 5, continued]

(5) [*Dependent and Multiple Dependent Claims*]¹ (a) Any claim which includes all the limitations of ~~another claim or several~~ one or more other claims (hereinafter referred to as “dependent claim” and “multiple dependent claim,” respectively) shall, preferably ~~in~~ 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 limitations claimed that are additional to the limitations claimed in the other claim or the other claims.

(b) 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 ~~M~~multiple dependent claims may refer in the alternative or in the cumulative to the claims on which ~~they~~ it depends.

(c) 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.

¹ 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 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 text of this Rule is subject to the outcome of the discussions in the Working Group on Multiple Invention Disclosures and Complex Applications.

Rule 7

Time Limit Under Article 7(1)

The time limit referred to in Article 7(1) shall be not less than two months from the date of the notification referred to in that Article.

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.

(b) For the purposes of Article 8 and this Rule, the term “public” means any person who is [free to disclose the information] [not bound by an obligation to maintain the information secret].

[*COMMENT: There is no substantive difference between the two alternative texts within square brackets.*]

(3) [*Determination of the Date of Availability to the Public*] Where information allows to ~~determine the determination of~~ determine 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 last day of that month or that year, respectively, unless any evidence proves otherwise.

Rule 9

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

(1) [*Principle of “Whole Contents”*] (a) The whole contents of an earlier application referred to in Article 8(2) shall consist of the description, claims and drawings ~~and, where it was prepared by the applicant, the abstract, on as of the filing date.~~

(b) ~~Notwithstanding Article 1(ii),~~ ~~†~~ The earlier 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) [*Earlier Application Claiming Priority*] The earlier application referred to in Article 8(2)(b) may claim the priority of a previous application for a patent, utility model or any other title protecting an invention under the applicable law.

(3) [*Applications No Longer Pending*] Where the earlier application referred to in Article 8(2) has been published in spite of the fact that, before the date of its publication, it was no longer pending with no rights outstanding, it shall not be considered as prior art for the purposes of that Article.

(4) [*Anti-Self-Collision*] Article 8(2) and paragraphs (1) to (3) shall not apply when the applicant in respect of, or the inventor identified in, the earlier 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] [a patent may not be validly granted with effect for a Contracting Party for a claimed invention which is not patently distinct from another claimed invention].

[COMMENT: The words “not patently distinct” in the second alternative presented within square brackets mean that two or more claimed inventions are patentable over each other. It should be noted that, in accordance with Article 8(2), earlier applications form part of the prior art for the purpose of determining only the novelty of the 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 Biologically Reproducible Material Under Article[s] 10 [and 11(3)]

(1) [*Deposit of Biologically Reproducible Material*] Where the application refers to a ~~deposit of~~ biologically reproducible material which ~~has been made~~ cannot be disclosed in the application in such a way as to enable the claimed invention to comply with Article[s] 10 [and 11(3)] and such material is not available to the public, the material shall be deposited with a depositary institution in accordance with Article 5(2), the requirement of sufficiency of disclosure under Article 10(1) shall be considered to be complied with by the deposit to the extent that this requirement cannot otherwise be complied with. 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. The words within square brackets are included in accordance with a suggestion made by one delegation to take into account the deposit of biologically reproducible material for the determination of the requirement concerning the relationship of claims to the disclosure under draft Article 11(3).]

(2) [*Time of Deposit*] (a) Subject to subparagraph (b), the deposit shall be made no later than the filing date of the application.

[Alternative A]

(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

[Rule 11(2), continued]

~~made in a manner~~ 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 ~~evidence~~ 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]

(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,

[Rule 11(2), continued]

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: (1) 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. (2) It should be noted that, as a general rule, requirements under Article[s] 10 [and 11(3)] may be fulfilled after the filing date by way of amending the claims, description or drawings, provided such amendment meets the requirement under Article 7(3), i.e., no new matter is included.]

(3) *[International Depositary Authority]* No Contracting Party shall refuse the effect of a deposit referred to in paragraph (1) if it has been made with an International Depositary Authority under the Budapest Treaty.

Rule ~~11bis~~12

Relationship of Claims to Disclosure Under Article 11(3)

The subject matter of each claim shall be supported by the ~~claims,~~ description and ~~the~~ 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 123

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, the mere fact that a claimed invention includes additional features not found in the examples disclosed in the application or patent, lacks features found in such examples or does not achieve every objective or possess every advantage cited or inherent in such examples shall not remove that claimed invention from the scope of the claims.

(3) [*Reference Signs*] Any reference signs to the applicable part of the drawing referred to in Rule 5(4)(c) shall not be construed as limiting the claims.

(4) [*Special Types of Claims*] (a) Where a limitation in the claim defines a means {or a step} in terms of its function or characteristics without specifying the structure or material {or act} in support thereof, such a limitation 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) Notwithstanding subparagraph (a), where the function is inherent in the means {or the step} and, therefore, does not define the means {or the step}, the limitation shall be construed as the means {or the step} *per se*.~~

[COMMENT: For the purpose of the interpretation of claims, subparagraph (a) shall apply to means (step)-plus-function claims. However, 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. For example, concerning a claim such as “chemical compound X having anti-cancer effect”, where the anti-cancer effect is an inherent characteristic of the chemical compound X, the claim would not involve novelty/inventive step (be obvious) having regard to prior art which refers to the “chemical compound X” as such.]

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

(~~dc~~) Where a limitation in the claim defines a product for a particular use, such a limitation shall be construed as the product being limited to such use only ~~if the product is used solely for that purpose and/or is particularly suitable for that use. Otherwise, the limitation shall be construed as the product *per se*.~~

[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. For example, a claim aimed at “a chemical compound Z for insecticidal use” may be patentable having regard to prior art which refers to the “chemical compound Z” as such, if the insecticidal use of the chemical compound Z is new.]

(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 ~~time of any alleged infringement,~~ 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, ~~and;~~ or

[Rule 13(5), continued]

- (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;

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: Alternative B is intended to provide a harmonized approach as regards the doctrine of equivalents. As regards item (i), the Practice Guidelines would 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 would 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]

(6) [*Prior Statements*] In determining the scope of protection conferred by the patent, due account shall be taken of any statement limiting the scope of the claims made by the applicant or the ~~owner of 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*] Any item of prior art relevant to the determination of lack of novelty (“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 ~~as of the date on which the primary item of prior art was made available to the public.~~

[COMMENT: Paragraph (1)(ii) provides the principle that the primary item of prior art shall be enabling. 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).]

(2) [*Scope of the Primary Item of Prior Art*] (a) The scope of the primary item of prior art shall be determined by what was explicitly or inherently disclosed, ~~to a person skilled in the art,~~ on the date on which the primary item of prior art was made available to the public. 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) For the purposes of subparagraph (a), the general knowledge of a person skilled in the art on the date on which the primary item of prior art was made available to the public shall be taken into account.~~

(eb) 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.

(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 paragraphs ~~(1) and~~ (2) shall be considered as a reference to the filing date of the earlier application or, where applicable under Article 8(2)(b), the priority filing date of the primary item of prior art previous application.

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 disclosed, to a person skilled in the art, as of the claim date.

(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 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 a person skilled in the art, on the claim date, to reach the claimed invention by substituting, combining or modifying one or more of those items of prior art.

Rule 136

Exceptions Under Article 12(5)

Contracting Parties may exclude from patentability:

[Reserved]

[End of document]