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## **STANDING COMMITTEE ON THE LAW OF PATENTS**

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DRAFT REGULATIONS AND PRACTICE GUIDELINES  
UNDER THE SUBSTANTIVE PATENT LAW TREATY

*prepared by the International Bureau*

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## INTRODUCTION

1. The present document contains a revised version of the draft 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 sixth session (November 5 to 9, 2001).
2. Differences between the former text of the draft Regulations Under the Substantive Patent Law Treaty contained in document SCP/6/3 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/6/3 but appear in the present text are underlined, and
  - (ii) words which appeared in document SCP/6/3 but which are omitted from the present document are shown as struck through.
3. As regards the draft Practice Guidelines, taking into account the discussions at the sixth session of the SCP (see paragraph 14 of the draft Report (document SCP/6/9 Prov. 2)), they have been re-worded in a more explicit style and provisionally included into the present document, together with the relevant Rule to which they belong.
4. 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.
5. Explanatory Notes on the provisions of the draft SPLT, draft Regulations and draft Practice Guidelines are contained in document SCP/7/5.

DRAFT REGULATIONS

*Rule 1*

*Abbreviated Expressions*

- (1) [~~“Treaty”; “Article”~~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) ~~It~~ For the purposes of these Regulations, unless expressly stated otherwise,
- (i) “general knowledge of a person skilled in the art” means the common knowledge ~~that generally known to a person skilled in the art~~ generally has, including well-known or commonly used information, or matters clear from empirical rules;
- (ii) “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 the Regulations.

*Rule 2*

*Person Skilled in the Art Under Articles ~~1(x)~~, 7(3)(~~eb~~), 10(1), 11(3)(b) and (4)(a) and 12(3), and Rules 1(c)(i), ~~54(1)(vii) and (2)(b)~~, ~~8(2)(b)~~, ~~10(1) and (2)(iii)~~, ~~11(1)~~, ~~12(15) and (3)(a)~~, 14(1)(ii), ~~and (2)(a) and (b)~~ and 15(2), (3) and (4)*

A person skilled in the art shall be ~~presumed to be an ordinary practitioner~~ considered to be a hypothetical person deemed to have~~ing~~ access to and to ~~understanding~~ all prior art under Article ~~8(1)~~, and to have ordinary skills and general knowledge, in the relevant field of the art at the relevant date, as prescribed in the Practice Guidelines.

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

G1.01 A person skilled in the art has ordinary skills and common knowledge to comprehend and use the prior art. This means that a person having ordinary skills in the art has at his/her disposal the ordinary means and capacity used by ordinary practitioner in the relevant field to conduct experimentation and analysis. The general knowledge referred to in Rule 2 is the common knowledge in the art as prescribed in draft Rule 1(c)(i). The general knowledge may be contained in handbooks or textbooks in a tangible form. However, it may also consist of unwritten knowledge well-known or commonly used in the field of the art concerned, for example, well-known laboratory techniques. In any event, the person skilled in the art shall not be required to possess any inventive capability in addition to the conditions set forth in Rule 2.

G1.02 The term “the relevant field of the art” may cover more than one field of the art, if the nature of the claimed invention suggests a link to other fields of the art. It is not necessarily limited to the specific field of the claimed invention, but may include the neighboring fields of the art as well as general (non-specific) fields dealing with general problems commonly applicable to the specific fields. The person skilled in the art may also refer to other fields which are neither neighboring nor general fields, as long as an average person skilled in the art would be expected to take those fields into account. In determining the prior art in the relevant field of the art, the following factors, in particular, shall be taken into account:

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

[Guidelines Under Rule 2, continued]

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

(iii) the prior art solutions to those problems.

G1.03 In view of the previous explanations, a person skilled in the art may be deemed to have the knowledge of a team of persons referred to in Rule 2, for example a research team or a number of persons skilled in different fields of the art.

*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;

(ii) [Reserved]



*Rule 4*

*Details Concerning the Right to a Patent Under Article 4*

~~(1) — [Employee's Inventions] [(a)] Any Contracting Party shall be free to determine the circumstances under which and the extent to which the right to the patent shall belong to the employer of the inventor or to the person who commissioned the work of the inventor which resulted in the invention.~~

~~(b) — Notwithstanding subparagraph (a), the law of the Contracting Party in which the employee performs his main activity under the employment contract shall be applicable for the determination of the right to the patent, except where the employment contract provides otherwise.~~

~~(2) — [Right to Invention Made Jointly by Several Inventors]~~

~~[Reserved]~~

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;
  - (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 invention, as claimed, in such terms that the ~~[technical]~~ 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;

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<sup>†</sup> ~~The inclusion of this provision is subject to the discussion on Article 5 and on document SCP/6/5.~~

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

(vi) set forth at least one mode for carrying out the claimed invention~~claimed~~; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any;

(vii) indicate explicitly, when it is not otherwise 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 shall be presented in the~~ a manner and or an order different than specified in paragraph (1), ~~unless 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 ~~does not contain the matters specified in paragraph (1)(i), (ii) and (v), or which~~ contains, in lieu of the matter specified in paragraph (1)(iii), a description of the claimed invention in any terms that satisfy the requirement of a disclosure of the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art allow the claimed invention to be understood.

[Rule 4, continued]

~~(3) — [Requirements Under the Patent Cooperation Treaty] Any Contracting Party shall apply the formal requirements concerning the disclosure of certain matters, for example, computer program listings, nucleotide or amino acid sequence listings or a deposit of biological material, which are applicable under the Patent Cooperation Treaty.~~

*Details Further Requirements Concerning Claims Under Article 5(2)*

(1) [*Consecutive Numbering*] Where the application contains several 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:-

~~(3) [*Elements of Claims*] Each claim shall consist of one or more limitations.~~

(43) [*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 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 ~~limitations~~ features which, in combination with the features stated in the first part, define the matter for which protection is sought; or

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<sup>2</sup> ~~The inclusion of this provision is subject to the discussion on Article 5 and on document SCP/6/5.~~

(ii) in a single part containing a recitation of a combination of several ~~elements~~  
~~or steps~~ ~~limitations~~, or a single ~~element or step~~ ~~limitation~~, which defines the matter for  
which protection is sought.

(54) [*References in the Claims to the Description and Drawings*] (a) No claim may,  
except where absolutely necessary, contain, ~~in respect of the~~ ~~technical~~ features of the  
~~invention~~, 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 ~~or graph~~. Any claim may contain tables,  
graphs and chemical or mathematical formulas.

(c) Where the application contains a drawing, the mention of any ~~technical~~  
~~feature~~ ~~limitation~~ in a claim may, if the intelligibility of that claim can thereby be enhanced,  
include a reference sign to ~~that drawing or to~~ the applicable part of that drawing; such a  
reference sign shall be placed between square brackets or parentheses; ~~it shall not be construed~~  
~~as limiting the claim~~.

~~(d) Where the application contains a nucleotide or amino acid sequence listing, a~~  
~~reference in the claim to the sequences represented in the sequence listing shall be made in~~  
~~accordance with WIPO Standard ST.25.~~

(65) [*Dependent and Multiple Dependent Claims*]<sup>3</sup> (a) Any claim which includes all the ~~{features}~~{limitations} of another claim ~~of the same category (product or process)~~ or several other claims ~~of the same category~~ (hereinafter referred to as “dependent claim” and “multiple dependent claim,” respectively) shall, preferably in 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}~~{limitations} claimed that are additional to the ~~{features}~~{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. Multiple dependent claims may refer in the alternative or in the cumulative to the claims on which they depend.

(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.}

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<sup>3</sup> The text of this Rule is subject to the outcome of the Working Group on Multiple Invention Disclosures and Complex Applications.

*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.

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<sup>4</sup> The text of this Rule is subject to the outcome of the Working Group on Multiple Invention Disclosures and Complex Applications.



*Rule ~~16~~7*

*Time Limit Under Article ~~15~~7(1)*

The time limit referred to in Article ~~15~~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*] ~~To qualify as prior art under Article 8(1),~~  
~~Information may be made available to the public in any form, such as~~ in written form, by oral  
communication, by display, ~~or through use, shall qualify as prior art under Article 8(1) or in~~  
~~any other form.~~

(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” ~~constitutes~~  
~~means any person, who may not be a person skilled in the art, and who is not bound by any~~  
~~restrictions regarding the use or dissemination of~~ free to disclose the information.

~~(3) [*Evidence of Non-Documentary Disclosure*] Where information is made available~~  
~~to the public in non-written form, a Contracting Party may require, for the information to~~  
~~qualify as prior art, corroborative evidence in order to establish the timing and the contents of~~  
~~the disclosure.~~

(43) [*Determination of the Date of ~~Publication~~ Availability to the Public*] Where information ~~in written form~~ allows to determine only the month or the year, but not the specific date, ~~of the publication~~ in which it was made available 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.

Guidelines Under Rule 8

(Details Concerning Prior Art)

G2.01 Rule 8 shall apply, *mutatis mutandis*, where the information was made available to the public through communication by electronic means, in particular via an electronic database or the Internet.

G2.02 The means by which the information was made accessible may offer some guidance on what constitutes a reasonable possibility referred to in Rule 8(2):

G2.03 *By oral communication*: The information shall be deemed to be made available to the public if the information was unconditionally brought to the knowledge of a member of the public through oral communication, such as a lecture or by means of radio or sound reproduction equipment (e.g., tapes and records).

G2.04 *By display or through use*: The information shall be deemed to be made available to the public if, on the relevant date, it was possible for a member of the public to gain knowledge of that information through the display or the use of the medium. For example, if a person sells an object unconditionally to a member of the public without limitation or restriction, or injunction or obligation of secrecy, the object shall be deemed to be made available to the public, since the buyer acquires unlimited possession of any knowledge which may be obtained from that object. In other words, whether the information is considered to be available to the public is determined by the extent of control placed on its access by the person initially possessing the information.

G2.05 In written form: A document shall be regarded as made available to the public if, at the relevant date, it was possible for a member of the public to gain knowledge of the contents of the document. Therefore, the member of the public shall have not only the possibility of gaining access, in the technical sense, to the information contained in the document, but also the possibility of acquiring possession of such information. Whether the absence of an index or a catalogue of the information constitutes inaccessibility of the information to the public or not shall be determined in accordance with this principle.

G2.06 Via an electronic database or the Internet: The availability of information disclosed via an electronic database or the Internet shall be considered in the same manner as other forms of disclosure, i.e., whether it was possible for a member of the public to gain knowledge of the information concerned or not. Accordingly, where the information disclosed on the Internet was made available to a limited circle of people, it is considered being made available to the public, provided no obligation to maintain secrecy was imposed. In order to determine whether the information disclosed on the Internet was made available on a particular date or not, the following factors, in particular, shall be taken into account:

- (i) public availability of the URL; (ii) possibility of search by a search engine;
- (iii) credibility of the web site.

G2.07 In accordance with Rule 8(2)(b), the public constitutes any person who is free to disclose the information. Therefore, it may be a single person, and does not need to be a person skilled in the art.

*Rule 9**Prior Art Effect of ~~Former~~Earlier Applications Under Article 8(2)*

(1) [*Principle of “Whole Contents”*] (a) Subject to paragraph (2), the whole contents of an ~~earlier~~~~former~~ application on the filing date, shall, ~~for the purpose of determining the novelty of an invention claimed in another application,~~ be considered as prior art on condition that the ~~former~~~~earlier~~ application or the patent granted thereon is published subsequently by the authority competent for the publication of that application or patent.

(b) For the purposes of subparagraph (a), the “whole contents” of an application consists of the description, claims and drawings and, where it was prepared by the applicant, the abstract.

(c) Notwithstanding Article 1(ii), the ~~former~~~~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 only one of those titles may be validly granted with effect for a Contracting Party for the same claimed invention.

(2) [*~~Former~~Earlier Application Claiming Priority*] Where the ~~former~~~~earlier~~ application referred to in paragraph (1)(a) claims the priority of an ~~earlier~~ previous application for a patent, utility model or any other title protecting an invention under the applicable law, subject matter that is contained in both the ~~former~~that earlier application and such ~~earlier~~that previous application, and is published subsequently in accordance with paragraph (1)(a), shall

be considered as prior art ~~in accordance with paragraph (1)(a)~~ from the priority date of the ~~former~~earlier application.

(3) [*Applications No Longer Pending*] Where the ~~former~~earlier application referred to in paragraphs (1)(a) and (2) has been published in spite of the fact that, before the date of its publication, it was ~~withdrawn or abandoned, was considered withdrawn or abandoned, or was rejected~~ no longer pending, it shall not be considered as prior art for the purposes of paragraphs (1)(a) and (2).

(4) [*Anti-Self-Collision*] Article 8(2) and paragraphs (1) to (3) shall not apply when the applicant of, or the inventor identified in, the ~~former~~earlier application and the applicant 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.

*Rule 10*

*Sufficiency of Disclosure Under Article 10*

~~(1) — [Details Concerning Disclosure] For the purposes of Article 10, the general knowledge of a person skilled in the art and the amount of experimentation required shall be taken into consideration.~~

(2) — [Details Concerning Undue Experimentation] 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 10*

(1) [*Deposit of Biologically Reproducible Material*] Where the application refers to a deposit of biologically reproducible material which cannot be disclosed in the application in such a way as to enable the invention to be carried out by a person skilled in the art and such material is not available to the public, the application shall be supplemented by a deposit of such material with a depositary institution. has been made 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.

(2) [*Time of Deposit*] (a) ~~No Contracting Party may require that~~ Subject to subparagraph (b), the deposit shall be made before no later than the filing date of the application.

(b) Where the deposit is 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 that the deposited biologically reproducible material is the biologically reproducible material specifically identified in the application as filed.

[Rule 11, continued]

(~~23~~) [*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 12*

*Interpretation of Claims Under Article 11(4)*

~~(1) [*Basis for the Interpretation*] The wording of the claims shall provide the primary basis for their interpretation. The description, the drawings and the general knowledge of a person skilled in the art at the time of filing shall form the secondary basis for the interpretation.~~

(21) [*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.

~~(32) [*No Limitation to Express Disclosure*] (a) The claims shall not be limited to the embodiments expressly disclosed in the application. In particular, the general knowledge of a person skilled in the art at the time of filing shall be taken into account.~~

(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 ~~an~~ claimed invention includes additional features

[Rule 12(2)(b), continued]

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*.

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

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

(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 any alleged infringement, it performs substantially the same function in substantially the same way and produces substantially the same result as the claimed element, and 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.

(6) [*Prior Statements*] In determining the scope of protection, due account shall be taken of any statement limiting the scope of the claims made by the applicant or the owner of the patent during procedures concerning the grant or the validity of the patent.

*Rule 13*

*Exceptions to Patentable Subject Matter Under Article 12(1~~5~~)*

(1) ~~—[Subject Matter Not Considered to Be Inventions]~~ The following shall not be considered as inventions under Article 12(1):

(i) ~~—mere discoveries;~~

(ii) ~~—abstract ideas as such;~~

(iii) ~~—scientific theories and mathematical methods as such;~~

(iv) ~~—aesthetic creations.~~

(2) ~~—[Exceptions to Patentability]~~ Contracting Parties may exclude from patentability:

[Reserved]<sup>5</sup>

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<sup>5</sup> 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.

*Rule 14*

*Items of Prior Art Under Article 12(2)*

(1) [Primary Item of Prior Art] ~~For the determination of lack of novelty,~~ Any items 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) ~~must~~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.

(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.

(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.

(c) 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.

[Rule 14, continued]

(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 or, where applicable, the priority date of the primary item of prior art.

~~(2) [Other Items of Prior Art] Notwithstanding paragraph (1), for the determination of novelty, items of prior art which would have been known to a person skilled in the art and which~~

~~(i) contribute to determining whether the primary item of prior art was enabling;~~

~~(ii) are incorporated by explicit reference in the primary item of prior art;~~

~~(iii) explain the meaning of terms used in the primary item of prior art; or~~

~~(iv) show that a characteristic not disclosed in the primary item of prior art is inherent,~~

~~shall be taken into account together with the primary item of prior art.~~



Guidelines Under Rule 14

(Methodology for Assessment of Novelty)

G3.01 For the assessment of novelty, the following steps shall be applied:

(i) determination of the claimed invention;

(ii) determination of a relevant item of prior art (“primary item of prior art”);

(iii) assessment whether every and each element or step of the claimed invention is found in the scope of the primary item of prior art as prescribed in Rule 14(2).

G3.02 Where a claim contains a specific disclosure, for the determination of novelty, a generic disclosure in the item of prior art does not anticipate the claim to a specific example falling within that generic disclosure, except where the specific example is clearly identified in the scope of the item of prior art.

G3.03 On the other hand, where a claim contains generic disclosure, for the determination of novelty, the disclosure of a specific example in the item of prior art falling within a claimed generic disclosure anticipates that generic disclosure. Similarly, where a claim contains alternatives, the claim is anticipated if one of the alternatives is within the scope of the item of prior art. Further, where a claim contains certain numeric ranges, the claim is anticipated if a specific example in the item of prior art falls within the claimed range.

[Guidelines Under Rule 14, continued]

G3.04 In accordance with the general principle concerning the submission of evidence under Article 16, in order to determine the scope of the primary item of prior art referred to in Rule 14(2) and to ensure that the primary item of the prior art is enabling under Rule 14(1)(ii), the following evidence shall be taken into account, where appropriate:

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

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

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

*Rule 15*

*Items of Prior Art Under Article 12(3)*

(1) [~~Multiple Items of Prior Art~~] ~~For the determination of inventive step (non-obviousness),~~ 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 ~~may be combined if there was any motivation for a person skilled in the art, on the claim date, to combine the 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.

(~~23~~) [~~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 ~~[time of filing 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.

Guidelines Under Rule 15

(Methodology for Assessment of Inventive step/Non-Obviousness)

G4.01 For the assessment of inventive step (non-obviousness), the following steps shall be applied:

(i) determination of the scope of the claimed invention;

(ii) determination of the scope of the relevant item(s) of prior art;

(iii) determination of a person skilled in the art in the relevant case;

(iv) identification of the differences and similarities between the relevant item(s) of prior art and the claimed invention;

(v) assessment whether the claimed invention as a whole would have been obvious for a person skilled in the art having regard to the relevant item(s) of prior art and the general knowledge of a person skilled in the art.

G4.02 In order to establish a *prima facie* case of obviousness and to determine whether there was any motivation, either in the prior art or in the general knowledge of a person skilled in the art as of the claim date, to modify, substitute or combine the teachings of the prior art, the following factors, in particular, shall be considered:

(i) relevance of the field of the art;

(ii) relevance of the problem to be solved;

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

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

G4.03 According to Rule 2, a person skilled in the art is deemed to have ordinary skills and general knowledge in the relevant field of the art. Common practices and experiments that normally require only ordinary skills in the art and the general knowledge are hence considered routine expedients by the person skilled in the art. Therefore, where, on the basis of the relevant items of prior art and the general knowledge, a person skilled in the art can reach the claimed invention by way of utilizing such routine expedients, the claimed invention shall be considered obvious. However, this would not apply if any other evidence shows that the claimed invention does in fact involve an inventive step (is non-obvious).

G4.04 In order to establish the positive assertion that the claimed invention involves an inventive step (non-obviousness), the following factors, in particular, shall also be taken into account as secondary considerations:

(i) whether the claimed invention fulfils a long-felt need;

(ii) whether the claimed invention overcomes a scientific prejudice;

[Guidelines Under Rule 15, continued]

(iii) whether others have previously attempted, but failed to achieve what the claimed invention achieves;

(iv) whether the claimed involves an unexpected result;

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

[End of document]