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DRAFT REGULATIONS AND PRACTICE GUIDELINES UNDER THE DRAFT SUBSTANTIVE PATENT LAW TREATY

prepared by the International Bureau

WIPO

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INTRODUCTION

1. The present document contains a revised version of the draft Regulations and Practice Guidelines 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 fifth session (May 14 to 19, 2001).

2. Differences between the former text of the draft Regulations and Practice Guidelines Under the Substantive Patent Law Treaty contained in document SCP/5/3 and the revised text contained in the present document have been highlighted as follows:

(i) words which did not appear in document SCP/5/3 but appear in the present text are underlined, and

(ii) words which appeared in document SCP/5/3 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. Explanatory Notes on the provisions of the draft SPLT, draft Regulations and draft Practice Guidelines are contained in document SCP/6/4.

DRAFT REGULATIONS

Rule 1

Abbreviated Expressions

[Reserved]

(1) ["*Treaty*"; "*Article*"] (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) In these Regulations, "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 <u>+02</u>

Persons Skilled in the Art Under Articles 1(x), 7(3)(c), 10(1), 11(3)(b)and 12(3), 18 and 20(3)(b), and Rules 35(2)(b), 8(2)(b), 10(1) and (2)(iii), 9, 10, 11(1) and [(2)], 12(1) and (3)(a), 13(3) and 14(1)(ii) and (2) and 15

A person skilled in the art shall be <u>considered presumed</u> to be an ordinary practitioner <u>having access to and understanding all prior art under Article 8(1)</u> reasonably well versed, but without highly specialized skills, in the relevant field of the art <u>at the relevant date</u>, <u>as</u> <u>prescribed in the Practice Guidelinesknowing the general knowledge in that field of the art at</u> the relevant date.

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<u>Rule 3</u>

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]

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Rule <u>24</u>

Details Concerning the Right to a Patent Under Article 24

(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]

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[Rule <u>35</u>1

Contents and Order of Description Under Article 5

(1) [*Contents of Description*] The description shall, after stating the title of the invention,

(i) specify the [technical] field or fields to which the 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 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 theadvantageous effects, if any, of the invention with reference to the background art;

(iv) where a deposit of biologically reproducible material is required under Rule 9<u>11</u>, 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 invention;

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

¹ The inclusion of this provision is subject to the discussion on Article 5 and on document <u>SCP/6/5.</u>

[Rule 5(1), continued]

(vi) set forth at least one mode for carrying out the 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 invention, the way or ways in which the invention satisfies the requirement of being useful or industrially applicable.

(2) [*Manner and Order of Presentation of Contents*] (a) The contents of the description shall be presented in the manner and order specified in paragraph (1), unless, because of the nature of the invention, a different manner or a different order would afford a better understanding or a more economical presentation.

(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 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.

(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, if any.]

[Rule 4<u>6²</u>

Details Concerning Claims Under Article 65

(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.

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

(4) [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 [technical features] [limitations] which, in combination with the features stated in the first part, define the matter for which protection is sought; or

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

(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.

(5) [*References in the Claims to the Description and Drawings*] (a) No claim may 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 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.

[Rule 6, continued]

(6) [*Dependent and Multiple Dependent Claims*] (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.]

Rule <u>57</u>

Details Concerning the Requirement of Unity of Invention Under Article 76

(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 <u>that define a contribution which each of those inventions, considered as a whole, makes over</u> <u>the prior art</u>. The expression "special [technical] features" shall mean those [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 are is claimed in a separate claims or as an alternatives within a single claim.

Rule <u>68</u>

Availability to the Public Under Article 8(1)

(1) [*Form of Availability to the Public*] To qualify as prior art under Article 8(<u>1</u>), information may be made available to the public in written form, by oral communication, by display, through use or in any other form.

(2) [*Accessibility to the Public*] (a) Information shall be deemed to have been <u>be</u> <u>made</u> available to the public, if it has actually been accessed by one or more members of the <u>public, or</u> if there <u>was is</u> a [reasonable] possibility that it could have been <u>be</u> accessed by one or more members of the public.

(b) For the purposes of Article 8 and this Rule, the public constitutes 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 the information.

(3) [Evidence of Non-Documentary Disclosure] [Reserved] 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.

(4) [Determination of the Date of Publication] Where information in written form allows to determine only the month or the year, but not the specific date, of the publication, 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.

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Rule 7<u>9</u>

Prior Art Effect of Certain Former Applications Under Article 98(2)

(1) [*Principle of "Whole Contents"*] (a) Subject to subparagraph (b)paragraph (2), the whole contents of a former application <u>on the filing date</u>, shall, for the purpose of determining the novelty [and non-obviousness] of an invention claimed in another application, be considered as prior art from the filing date or, where priority is claimed, the priority date of the former application on condition that the former application or the patent granted thereon is published subsequently by the authority competent for the publication of that application or patent.

(eb) For the purposes of subparagraph (a), the "whole contents" of an application consists of the description, <u>claims</u> and any drawings, as well as the claims, but not the abstract.

(dc) Any Contracting Party shall consider an application for a utility as prior art in accordance with paragraph (a). Notwithstanding Article 1(ii), the former 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.

(b2) [Former Application Claiming Priority] Where the former application referred to in subparagraph (1)(a) claims the priority of an earlier application for a patent, utility model or any other title protecting an invention, matter that is contained in both the former application and such earlier application shall be considered as prior art in accordance with subparagraph (1)(a) from the priority date of the former application. [Rule 9, continued]

(23) [Applications No Longer Pending] Where the former application referred to in paragraph (1)(a) 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, it shall not be considered as prior art for the purposes of paragraph (1)(a).

(34) [*Self-Collision*] <u>Article 8(2) and Pparagraphs</u> (1) to (3) shall not apply when the applicant of, or the inventor identified in, the former application, and the applicant of, or the inventor identified in, the application under examination, is are, at the filing date of the application under examination, one and the same person, provided that only one patent may be validly granted by the same Office with effect for a Contracting Party for the same claimed invention.

Rule <u>810</u>

Sufficiency of Disclosure Under Article 1110

(1) [Details Concerning Disclosure] For the purposes of Article 4410,

(i) the claims as submitted upon filing shall be considered as forming part of the disclosure of the invention contained in the application as filed for the purposes of the filing date;

(ii)—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;

[Rule 10(2), continued]

(vi) the amount of experimentation required to make or use the claimed

invention on the basis of the disclosure.

Rule <u>911</u>

Deposit of Biologically Reproducible Material Under Article 4410

(1) [Deposit of Biologically Reproducible Material] Where the application refers to 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. No Contracting Party may require that the deposit be made before the filing date of the application.

(2) [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 11

Interpretation of Claims Under Article 14

(1) [*Principle*] For the purposes of Article 14(1), the claims shall be so interpreted as to combine fair protection for the applicant with a reasonable degree of certainty for third parties. Consequently, the claims shall not be interpreted as being necessarily confined to their strict literal wording. Neither shall the claims be considered as mere guidelines allowing that the protection conferred by the application extends to what, from a consideration of the description and drawings by a person skilled in the art, the applicant has contemplated, but has not claimed.

[(2) [*Equivalents*] For the purposes of Article 14(2), an element shall generally be considered as being equivalent to an element as expressed in a claim 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 element as expressed in the claim, and it is obvious to a person skilled in the art that the same result as that achieved by means of the element as expressed in the claim can be achieved by means of the equivalent element.

(3) [*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 during procedures concerning the grant or the validity of the patent.]

[Rule 11, continued]

(4) [*Examples*] If the application contains examples of the embodiment of the invention or examples of the functions or results of the invention, the claims shall not be interpreted as limited to those examples; in particular, the mere fact that a product or process includes additional features not found in the examples disclosed in the 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 the product or process from the scope of protection conferred by the claims.]

(5) [*Abstract*] The abstract shall not be taken into account for the purpose of determining the protection conferred by the claims.

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Rule 12

Definition of "Industry" Under Article 16

For the purposes of industrial applicability (utility), "industry" shall be understood in its

broadest sense, as in Article 1(3) of the Paris Convention for the Protection of Industrial

Property.

<u>Rule 12</u>

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.

(2) [*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.

(3) [*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; in particular, the mere fact that an 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 invention from the scope of the claims. [Rule 12, continued]

(4) [Special Types of Claims] (a) Where a limitation in the claim defines a means in terms of its function or characteristics without specifying the structure or material in support thereof, such a limitation shall be construed as defining any structure or material 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 and, therefore, does not define the means, the limitation shall be construed as the means *per se*.

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

(d) Where a limitation in the claim defines a substance or composition for a particular use, such a limitation shall be construed as the substance or composition being limited to such use only if the substance or composition 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 *per se*.

<u>Rule 13</u>

Exceptions to Patentable Subject Matter Under Article 12(1)

(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]³

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

Rule 1314

Items of Prior Art Under Article 1712(2)

(1) [Enabling Prior Art]

[Reserved]

(21) [*Primary <u>Item of Prior ArtReference</u>*] For the determination of <u>lack of novelty</u>, items of prior art

(i) may only be taken into account individually and may not be combined, and

(ii) must enable a person skilled in the art to make and use the claimed invention.

(32) [Other Items of Prior Art] Notwithstanding paragraph (21), for the determination of novelty, items of prior art which would have been known to a person skilled in the art, and which

- (ai) contribute to determining whether the primary reference item of prior art was enabling;
- (bii) are incorporated by <u>explicit</u> reference in the primary reference item of prior art;

[Rule 14(2), continued]

- (e<u>iii</u>) explain the meaning of terms used in the primary reference-<u>item of prior art;</u> or
- (div) show that a characteristic not disclosed in the primary reference-item of $\frac{\text{prior art is inherent}}{\text{prior art is inherent}}$

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

Rule 14<u>15</u>

Items of Prior Art Under Article <u>1812(3)</u>

(1) [Multiple Items of Prior Art] For the determination of inventive step
(non-obviousness), 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) [*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 <u>on the</u> [time of filing on the] claim date shall be taken into account.

<u>Rule 16</u>

Time Limit Under Article 15(1)

The time limit referred to in Article 15(1) shall be not less than two months from the

date of the notification referred to in that Article.

DRAFT PRACTICE GUIDELINES

[Guideline [...]

Lengthy Applications Under Article 4

A Contracting Party may require that an application comprising more than [...] pages in

A4 format be filed by electronic means and in electronic form, as prescribed in the

Regulations.]

[Guideline [...]

Methodology Under Article 18

[Reserved]

Guideline Under Rule 2

Details Concerning Person Skilled in the Art Under Rule 2

(1) [General Knowledge] A person skilled in the art shall be presumed to have the general knowledge in the relevant field of the art at the relevant date.

(2) [*Team of Persons*] The person skilled in the art may be a team of specialists, such as a research team or a number of specialists skilled in different fields of the art.

Guideline Under Rule 8

Details Concerning Prior Art

Rule 8(3) shall apply, *mutatis mutandis*, where the information was made available to the public through communication by electronic means, in particular, the Internet.

Guideline Under Rule 14

Methodology for Assessment of Novelty

(1) [Generic Disclosure] For the determination of novelty, a generic disclosure in the prior art does not anticipate a claim to a specific example falling within that generic disclosure, except where the specific example is clearly identified in the prior art.

(2) [Specific Disclosure] For the determination of novelty, the disclosure of a specific example in the prior art falling within a claimed generic disclosure anticipates that generic disclosure.

(3) [*Items of Prior Art Under Rule 14(2)(iv)*] For the purposes of Rule 14(2)(iv), evidence showing that a characteristic not disclosed in the primary item of prior art was inherent on the claim date may be taken into consideration.

Guideline Under Rule 15

Methodology for Assessment of Inventive Step/Non-Obviousness

(1) [*Test for Assessing Inventive Step/Non-Obviousness*] For the assessment of inventive step/non-obviousness, the following steps shall be applied:

(i) determination of the relevant prior art;

(ii) determination of the characteristics of the claimed invention;

(iii) identification of the differences and similarities between the prior art and the claimed invention;

(iv) assessment whether the claimed invention as a whole would have been obvious for a person skilled in the art.

(2) [Secondary Considerations] In determining inventive step/non-obviousness under paragraph (1), the following, in particular, shall be taken into consideration:

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

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

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

(iv) whether the claimed invention involves an unexpected result;

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

[End of document]