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PROPOSED AMENDMENT OF PCT RULE 13*bis*
"MICROBIOLOGICAL INVENTIONS"

Proposal by the European Patent Office

The Annex to this document contains a proposal by the European Patent Office for amendment of PCT Rule 13*bis* to reflect recent amendments of Rule 28 of the Implementing Regulations to the Convention on the Grant of European Patents (EPC) relating to the deposit of "biological material" for the purposes of the European patent grant procedure, including provisions relating to the deposit of biological material by a person other than the applicant.

[Annex follows]

ANNEX

INFORMATION FROM THE EUROPEAN PATENT OFFICE concerning the main amendments to Rule 28 EPC

1. Introduction

In its decision dated 14 June 1996 (OJ EPO 1996, 390 ff) the Administrative Council amended Rules 28 (and 28a) EPC relating to the deposit and new deposit of biological material for the purposes of the European patent grant procedure with effect from 1 October 1996. The new Rule 28 EPC is annexed (see 4).
The most important amendments, together with the main measures which have been or will be taken to implement them, are outlined below.

Theses amendments, as outlined below have a certain impact on PCT Rule 13bis (see also WIPO Circular PCT 608/211, page 3, 4).

2. Main amendments to Rule 28 EPC

2.1 Replacement of "micro-organism" by "biological material"

The word "micro-organism" has been replaced by **"biological material"** - meaning any material containing genetic information and capable of self-reproducing or of being reproduced in a biological system (Rule 28(6)(a) EPC). The amendment thus uses the same terminology as the old and new draft EU directives on the legal protection of biotechnological inventions, which has not been controversial.

The term "micro-organism" as used in previous Rule 28 EPC and the Budapest Treaty is not defined, and was in line with the state of industrial microbiology at the time, which was based essentially on the use of bacteria and yeasts.

Technological advances soon made it necessary to expand the concept to include biological elements which are not strictly speaking micro-organisms, to permit sufficient disclosure within the meaning of Article 83 EPC of inventions which in themselves are perfectly patentable. Thus the Guidelines for Examination in the EPO (C-IV, 3.5) have already been amended to specify that "micro-organism" also covers plasmids and viruses - in line with the practice at numerous depositary institutions recognised by the EPO.

The amendment to Rule 28 EPC allows deposits, supplementing written disclosure of the invention, of types of biological material not covered by current EPO practice, eg seeds.

Although the term "biological material" in principle makes possible the deposit for disclosure purposes of macroscopic or multicellular material such as seeds or plants, a deposit's admissibility under Rule 28 EPC

- in no way prejudges the deposited matter's patentability under Articles 52 to 57 EPC;

- does not deprive EPO departments of their powers to interpret the definition of "biological material" with a view to the disclosure requirement of Article 83 EPC;

- presupposes that a recognised depositary institution is prepared to accept the deposit of a given type of biological material.

2.2 Applicant and depositor not identical (Rule 28(1)(d) EPC)

Following board of appeal decision T 118/87 (OJ EPO 1991, 474) EPO practice has in principle been to consider the requirements of previous Rule 28 to be met only if the applicant and depositor are one and the same (see Guidelines C-II, 6), because consent to the deposited culture being made available to the public in accordance with this rule (Rule 28(2), last sentence, EPC) can only be given by the depositor entitled to dispose of it.

In order to meet applicants' requirements, a sub-paragraph (d) has been added to Rule 28(1) EPC which specifies that the biological material **may be deposited by a person other than the applicant** if the name and address of the depositor are stated in the application and a document is submitted satisfying the EPO that the latter has authorised the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the material being made available to the public in accordance with Rule 28.

The name and address of the depositor and proof of his consent must be submitted to the EPO within the periods laid down in Rule 28(2) EPC. No request for such information is issued by the EPO. Nor may such information be submitted after expiry of the relevant time limit (see G 2/93, OJ EPO 1995, 275).

2.3 Further changes (i.e. extension of the expert option (Rule 28(4) EPC) certification of requests for issue of a sample after grant of the European patent (Rule 28(7) EPC) are without impact on Rule 13bis PCT.

3. Proposal for amending Rule 13bis with respect to EPC Rule 28 (1)(d)

As already indicated in WIPO Circular PCT 608/211, page 3 and 4 it is proposed

- to replace the term "microorganism" by "biological material" and
- to provide for the case where the biological material has been deposited by a person other than the applicant, i.e. requirement to **proof** the **depositor's consent** (see above 2.2).

In addition reference is made to PCT Gazette No. 49/1996, p. 21263 concerning the EPO's requirements in this respect.

4. New Rule 28 EPC

Deposit of biological material

(1) If an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 if:

(a) a sample of the biological material has been deposited with a recognised depositary institution not later than the date of filing of the application;

(b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material;

(c) the depositary institution and the accession number of the deposited biological material are stated in the application, and

(d) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is submitted satisfying the European Patent Office that the latter has authorised the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with this Rule.

(2) The information referred to in paragraph 1(c) and, where applicable, (d) may be submitted

(a) within a period of sixteen months after the date of filing of the application or, if priority is claimed, after the priority date, this time limit being deemed to have been met if the information is communicated before completion of the technical preparations for publication of the European patent application;

(b) up to the date of submission of a request for early publication of the application;

(c) within one month after the European Patent Office has communicated to the applicant that a right to inspect the files pursuant to Article 128, paragraph 2, exists.

The ruling period shall be the one which is the first to expire. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited biological material being made available to the public in accordance with this Rule.

(3) The deposited biological material shall be available upon request to any person from the date of publication of the European patent application and to any person having the right to inspect the files pursuant to Article 128, paragraph 2, prior to that date. Subject to paragraph 4, such availability shall be effected by the issue of a sample of the biological material to the person making the request (hereinafter referred to as "the requester").

Said issue shall be made only if the requester has undertaken vis-à-vis the applicant for or proprietor of the patent not to make the biological material or any biological material derived therefrom available to any third party and to use that material for experimental purposes only, until such time as the patent application is refused or withdrawn or deemed to be withdrawn, or before the expiry of the patent in the designated State in which it last expires, unless the applicant for or proprietor of the patent expressly waives such an undertaking.

The undertaking to use the biological material for experimental purposes only shall not apply in so far as the requester is using that material under a compulsory licence. The term "compulsory licence" shall be construed as including ex officio licences and the right to use patented inventions in the public interest.

(4) Until completion of the technical preparations for publication of the application, the applicant may inform the European Patent Office that

(a) until the publication of the mention of the grant of the European patent or,
where applicable,

(b) for twenty years from the date of filing if the application has been refused or withdrawn or deemed to be withdrawn,

the availability referred to in paragraph 3 shall be effected only by the issue of a sample to an expert nominated by the requester.

(5) The following may be nominated as an expert:

(a) any natural person provided that the requester furnishes evidence, when filing the request, that the nomination has the approval of the applicant;

(b) any natural person recognised as an expert by the President of the European Patent Office.

The nomination shall be accompanied by a declaration from the expert vis-à-vis the applicant in which he enters into the undertaking given pursuant to paragraph 3 until either the date on which the

patent expires in all the designated States or, where the application has been refused, withdrawn or deemed to be withdrawn, until the date referred to in paragraph 4(b), the requester being regarded as a third party.

(6) Within the meaning of this Rule:

(a) biological material shall mean any material containing genetic information and capable of self-reproducing or of being reproduced in a biological system;

(b) for the purposes of paragraph 3, derived biological material is deemed to be any material which still exhibits those characteristics of the deposited material which are essential to carrying out the invention. The undertaking referred to in paragraph 3 shall not impede a deposit of derived biological material, necessary for the purpose of patent procedure.

(7) The request provided for in paragraph 3 shall be submitted to the European Patent Office on a form recognised by that Office. The European Patent Office shall certify on the form that a European patent application referring to the deposit of the biological material has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of that material. After grant of the European patent, the request shall also be submitted to the European Patent Office.

(8) The European Patent Office shall transmit a copy of the request, with the certification provided for in paragraph 7, to the depositary institution as well as to the applicant for or the proprietor of the patent.

(9) The President of the European Patent Office shall publish in the Official Journal of the European Patent Office the list of depositary institutions and experts recognised for the purpose of this Rule.

[End of Annex and of document]