

Decision of the Administrative Council of 14 June 1996 amending the Implementing Regulations to the European Patent Convention

THE ADMINISTRATIVE COUNCIL OF THE EUROPEAN PATENT ORGANISATION

Having regard to the European Patent Convention ("EPC"), and in particular Article 33(1)(b) thereof,

On a proposal from the President of the European Patent Office,

Having regard to the opinion of the Committee on Patent Law,

HAS DECIDED AS FOLLOWS:

Article 1

Rules 28 and 28a EPC shall be amended to read as follows:

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 depository 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 depository 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.

Rule 28a EPC

New deposit of biological material

(1) If biological material deposited in accordance with Rule 28, paragraph 1, ceases to be available from the institution with which it was deposited because:

(a) the biological material is no longer viable, or

(b) for any other reason the depositary institution is unable to supply samples,

and if no sample of the biological material has been transferred to another depositary institution recognised for the purposes of Rule 28, from which it continues to be available, an interruption in availability shall be deemed not to have occurred if a new deposit of the biological material originally deposited is made within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution and if a copy of the receipt of the deposit issued by the institution is forwarded to the European Patent Office within four months from the date of the new deposit stating the number of the application or of the European patent.

(2) In the case provided for in paragraph 1(a), the new deposit shall be made with the depositary institution with which the original deposit was made; in the cases provided for in paragraph 1(b), it may be made with another depositary institution recognised for the purposes of Rule 28.

(3) Where the institution with which the original deposit was made ceases to be recognised for the purposes of Rule 28, either entirely or for the kind of biological material to which the deposited sample belongs, or where that institution discontinues, temporarily or definitively, the performance of its functions as regards deposited biological material, and the notification referred to in paragraph 1 from the depositary institution is not received within six months from the date of such event, the three-month period referred to in paragraph 1 shall begin on the date on which this event is announced in the Official Journal of the European Patent Office.

(4) Any new deposit shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited.

(5) If the new deposit has been made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977, the provisions of that Treaty shall prevail.

Article 2

This decision shall enter into force on 1 October 1996.

Done at Berlin, 14 June 1996

For the Administrative Council
The Chairman

Julían ÁLVAREZ ÁLVAREZ