

RO – ROMANIA

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1. Requirements for Deposit

(1) Where an invention relates to a biological material or to the use of a biological material which was not available to the public and cannot be described in the patent application in a way which should enable a person skilled in the art to carry out the invention, the invention may be deemed to be disclosed, according to the provisions of Art. 18 paragraph (1)¹ only if:

(a) a sample of biological material was deposited with an international depositary authority, prior to the date of filing the application or the date of the recognized priority;

(b) the patent application, as filed, contains relevant information available to the applicant with regard to the features of the biological material;

(c) the patent application comprises the indication of the international depositary authority and the order number of the deposited biological material.

(2) Where the biological material was deposited by another person than the applicant, the name and the address of the depositor shall be mentioned in the patent application, and a document shall be submitted to OSIM to prove that the depositor authorized the applicant to make reference in the patent application to the deposited biological material, and unreservedly and irrevocably consented to render the deposited material available to the public, according to Art. 74.

(3) The information mentioned in paragraph (1) letter (c) and paragraph (2), as the case may be communicated:

(a) within 16 months from the filing date or, if a priority is claimed, from the priority date, the time limit being considered to be observed if the information is communicated until the end of the technical procedures with the view of publishing the patent application;

¹ As the current text of the Implementing Regulations, from which the quoted passages are taken, has not yet been updated, following the latest amendments of the Paten Law, the reference to Art. 18, para (1) should be replaced with Art. 17, para (1), according to the current version of the Law.

(b) up to the date of presenting the request for publication of the patent application, in compliance with Art. 23, paragraph (3)² of the Law;

(c) the time limit to expire first is applicable.

(4) After the communication of this information, the applicant shall be considered to consent unreservedly and irrevocably to render the deposited biological material, available to the public, according to Art. 74.

(Art. 17 (2), Patent Law 64/1991, as amended and republished in 2014; Art. 73, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991)

2. Time of Deposit

The deposit must be made with an international depositary authority prior to the date of filing of the application or the date of the recognized priority.

Art. 73, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991.

3. Duration of Storage

No provision.

4. Conditions for the Furnishing of Samples

(i) Access to the Biological Material Deposit

(1) The biological material deposited, according to Art. 73, may be accessed based on a request, by any person, starting on the date of publication of the patent application, the access being made by the delivery of a sample of deposited biological material to the interested person under the proviso of Art. 75.

(2) Delivering the sample of deposited biological material, mentioned in paragraph (1) shall be made only when the interested person makes the commitment before the applicant or patent owner not to communicate the biological material or a derived biological material to third parties and to use the biological material only for experimental purposes up to the date when the patent application is rejected, withdrawn or considered to be withdrawn, as the case may be, except where the applicant or patent owner expressly gives up such a commitment.

² As the current text of the Implementing Regulations, from which the quoted passages are taken, has not yet been updated, following the latest amendments of the Patent Law, the reference to Art. 23 para (3) should be replaced with Art. 22, para (3), according to the current version of the Law.

- (3) The commitment to use the biological material only for experimental purposes shall not be applicable when the interested person makes use of this material for an exploitation which results from a compulsory license.
- (4) The expression “compulsory license” mentioned in paragraph (3) includes the ex officio licenses and any right to use a patented invention for the interest of public.
- (5) “Derived biological material” is, within the meaning of paragraph (2), any material having the essential features of the deposited material for carrying out the invention.
- (6) The request provided for in paragraph (1) accompanied by the proof of payment of the fee for the certification of an official document shall be addressed to OSIM that certifies both the filing of a patent application referring to a biological material deposit and the fact that the interested person or the expert appointed by that person, in compliance with Art. 75, is entitled to deliver a sample of this material.
- (7) The request provided for in paragraph (1) may be addressed to OSIM even after the grant of the patent.
- (8) OSIM shall transmit a copy of the request referred to in paragraph (1), accompanied by the certification referred to under paragraph (6) both to the international depositary authority and to the applicant or patent owner.

(Art. 74, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991)

(ii) Appointment of an expert

- (1) Up to the end of the technical preparations for the publication of the patent application, the applicant may communicate to OSIM that:
 - (a) up to the publication of the mention of the decision to grant the patent, in compliance with Art. 23 paragraph (4)³ of the Law; or, where appropriate,
 - (b) for a 20-year period starting from the patent application filing date, if the patent application is rejected, withdrawn or considered to be withdrawn, the access provided for in Art. 74 can be allowed only by delivering a sample of biological material to an expert appointed by the interested person.
- (2) The appointed expert may be:
 - (a) any natural person, provided that the interested person, according to paragraph (1), makes the evidence that, on the date of filing the request for the delivery of the sample, the appointment of the expert was made with the agreement of the applicant;

³ As the current text of the Implementing Regulations, from which the quoted passages are taken, has not yet been updated, following the latest amendments of the Patent Law, the reference to Art. 23, para (4) should be replaced with Art. 22, para (4), according to the current version of the Law.

(b) any natural person that is recognized to be an expert by OSIM.

(3) The appointment mentioned in paragraph (2) is accompanied by a statement made by the expert whereby this assumes the commitment to the applicant in compliance with Art. 74 and the fact that, either up to the date of the patent expiration or up to the date provided for in paragraph (1) letter b), the patent application may be rejected, withdrawn or deemed being withdrawn, the interested person being deemed to be a third party.

(Art. 75, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991).

Besides the provisions presented above, under the entries indicated in your letter, the current version of the Implementing Regulations of the Patent Law 64/1991, as republished, also comprises the following provisions:

New deposit of biological material

(1) If the biological material deposited according to Art. 73 paragraph (1) ceases to be available with the international depositary authority, there shall not be considered a discontinuity of its availability if the following conditions are fulfilled cumulatively:

- (a) a new deposit is constituted in compliance with the Budapest Treaty;
- (b) a copy of the document issued by the international depositary authority, confirming the receiving of the new deposit and in which the application or patent number is mentioned, is sent to OSIM within four months from the date of the new deposit.

(Art. 76, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991).

Description of the invention relating to microorganisms

(1) If the subject-matter of the invention relates to a new microorganism strain, the description of the invention shall contain, within the embodiment of the invention, at least one process for obtaining said microorganism, besides the morphological and biochemical features of the microorganism; in the description there shall also be indicated the taxon integration of the microorganism, number of order and date of depositing the microorganism with the international depositary authority where the microorganism was deposited.

(2) If the subject-matter of the invention related to a product containing a microorganism or obtained by means of a process involving a microorganism, or to a process in which a microorganism is involved, the description of the invention shall contain in the embodiment the taxon integration, the morphological and biochemical

features of the microorganism, denomination of the microorganism, number of order and date of depositing the microorganism with the international depositary authority, as well as the denomination of the international depositary authority where the used microorganism has been deposited.

(Art. 78, Implementing Regulations of the Patent Law 64/1991, approved by the Government Decision No. 547/2008 for approval of the Implementing Regulations of the Patent Law 64/1991).