

Appendix C

Proposed Rules on Deposit

Department of Commerce

Patent and Trademark Office
37 CFR Part 1

Deposit of Biological Materials for Patent Purposes;
Notice of Proposed Rulemaking
October 6, 1988

(a) Deposit of Biological Material

Section 1.200 Biological material.
Section 1.201 Need to make a deposit.
Section 1.202 Acceptable depository.
Section 1.203 Time of making an original deposit.
Section 1.204 Replacement of deposit.
Section 1.205 Term of deposit.
Section 1.206 Viability of deposit.
Section 1.207 Furnishing of samples.
Section 1.208 Examination procedures.

Section 1.200: Biological material.

For the purposes of these regulations pertaining to the deposit of biological material for patent purposes, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds. Viruses, vectors, cell organelles, and other nonliving material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the nonliving material.

Section 1.201: Need to make a deposit.

(a) Where a claimed invention is, or relies on, a biological material which is not known and readily available to the public and which cannot be described in writing alone, the disclosure may include a deposit of a biological material deposited in a depository and under conditions complying with these regulations.

(b) Biological material need not be deposited if it is known and readily available to the public or can be made or isolated without undue experimentation from known and readily available material. Samples will be **considered** to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health, or similar reasons.

(c) The reference to a specific organism or other biological material in a specification disclosure does not create any presumption that the specific material is necessary to satisfy 35 U.S.C. 112 or that a deposit in accordance with these regulations is required.

Section 1.202: Acceptable depository.

(a) A deposit shall be made in:

(1) Any International Depository Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Commissioner may seek the advice of impartial consultants from the biotechnology industry or governmental agencies on the suitability of a depository. The depository must:

- (i) Have a continuous existence;
- (ii) Exist independent of the control of the depositor;
- (iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;
- (iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;
- (v) Be impartial and objective; and
- (vi) Furnish samples of the deposited material in an expeditious and proper manner.

(b) If any depository under paragraph (a) of this section defaults or discontinues the performance of any of the tasks it should perform, the Office will recognize as a substitute in any pending application or patent a deposit, which must be viable if the biological material is of a kind capable of self-replication, made with an IDA or deposi-

tory recognized to be suitable by the Office which is transferred to said depository from the defaulting depository in the manner required for replacing a deposit under Section 1.204.

(c) A depository seeking status under paragraph (a) (2) of this section must direct a communication to the Commissioner which shall:

(1) Indicate the name and address of the depository to which the communication relates;

(2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (b) of this section, including information on its legal status, scientific standing, staff and facilities;

(3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;

(5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(d) A depository having status under paragraph (a) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Commissioner in accordance with paragraph (c) of this section. If a previous communication under paragraph (c) of this section is of record, items in common with the previous communication may be incorporated by reference.

(e) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office.

Section 1.203: Time of making an original deposit.

(a) An original deposit maybe made at any time before filing an application for patent or, pursuant to a requirement that will be made by the examiner no later than the date the Notice of Allowance and Issue Fee Due is mailed, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant shall promptly submit a verified statement from a person in a position to corroborate the fact, and shall state, that the biological material which is deposited is the same biological material described in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified.

Section 1.204: Replacement of deposit

(a) Where a depository possessing the original deposit cannot furnish samples of the deposit for any reason, the depository shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof. Subject to paragraphs (e), (f), and (g) of this section, the depositor shall be required to make a replacement deposit of the biological material which was originally deposited within three months of receiving notification that the depository cannot furnish samples. The period for satisfying this requirement is extendable upon petition, only for sufficient cause, and for a reasonable time specified. Any request for such extension must be filed on or before the day on which the action is due, but in no case will the mere filing of the request effect any extension. The replacement shall be made in any acceptable depository under Section 1.202(a).

(b) An applicant or patent owner shall notify the Office in writing, in each application or patent affected, as soon as reasonably possible after a replacement deposit is made. This notification shall state the name and address of the depository, the accession number for the deposit, the date of making the deposit, the results of a viability test if applicable (as Provided for in Section 1.206), the reason for making the replacement deposit, and include a verified statement, except that if made by an attorney or agent registered to practice before the Office, the statement need not be verified. If the replacement deposit relates to a pending application, the statement shall be by a person in a position to corroborate the fact, and shall state, that the biological material which is deposited as a replacement is identical to that originally deposited. The notification shall be placed in the relevant application or patent file.

(c) A depositor's failure to replace a deposit within the time required by this section may cause the application or patent involved to be treated in any office proceeding as if no deposit were made.

(d) In the event a deposit is replaced, the Office will apply a rebuttable presumption of identity between the original and the replacement deposit is relied upon during any Office proceeding.

(e) Where an application is still pending, the time for making a replacement deposit shall be the same as the time for making an original deposit under Section 1.203(a). The applicant shall promptly notify the Office after receiving notice that the depository possessing the original deposit cannot furnish samples of the deposit for any reason. A replacement deposit may be made during this time for any reason, including where the depository can furnish samples but the original deposit has become contaminated or has lost its capability to function as described in the specification.

(f) In no case is a replacement deposit of a biological material necessary where the biological material, in accordance with Section 1.201(b), need not be deposited.

(g) No replacement deposit of the biological material is necessary where a viable deposit is in the depository but the depository for national security, health or environmental safety reasons is unable to provide samples to requesters outside of the jurisdiction where the depository is located.

(h) A patentee may not replace a viable deposit where the depository can furnish samples. Nothing in these regulations is intended to prohibit a patentee from making an additional deposit of a biological material where an earlier deposit, otherwise viable, has become contaminated or has lost its capability to function as described in the specification.

Section 1.205: Term of deposit.

A deposit shall be made for a term of at least thirty (30) years after the date of a viable deposit and at least five (5) years after the most recent request for the furnishing of a sample of the deposited biological material was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

Section 1.206: Viability of deposit.

(a) A deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. No evidence is necessarily required regarding the ability of the deposited material to perform any function described in the patent application.

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

(c) If a viability test indicates that the deposit is not viable upon receipt, or the examiner cannot, for scientific or other valid reasons, accept the statement of viability

received from the applicant, the examiner shall proceed as if no deposit has been made. The examiner will accept the conclusion set forth in a viability statement issued by a depository recognized under Section 1.202(a).

Section 1.207: Furnishing of samples.

(a) The deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under Section 1.14 and 35 U.S.C. 122 and

(2) Subject to paragraphs (b) and (c) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depository may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, **during the term of the patent:**

- (1) Is in writing, signed and dated;
- (2) Contains the name and address of the requesting party and the accession number of the deposit; and
- (3) Is communicated in writing by the depository to the depositor along with a copy of the request, the date on which the sample was furnished, and the name and address of the party to whom the sample was furnished.

(c) the depositor may require that sample of a deposited biological material shall be furnished only if the requesting party has agreed in writing, not to make the deposited biological material or any biological material derived therefrom available during the term of the patent to any third party without the written permission of the depositor, and to assume the burden of proof concerning compliance with the agreement. With the exception of the Commissioner and an acceptable depository under Section 1.202 in which the requesting party has made a new deposit for patent purposes of the deposited biological material or any biological material derived therefrom, any person or entity other than the requesting party and the depositor shall be deemed to be a third party under this paragraph. For the purposes of this paragraph, any biological material shall be deemed to be derived from the deposited biological material if it is replicated from, or would not have been produced but for access to, the deposited biological material, provided that the derived matter still exhibits the essential characteristics of the deposited biological material.

(d) Upon request, the Office will certify whether the deposit has been stated to have been made under conditions which make it available to the public as of the

issue date of the patent grant provided the request contains:

- (1) The name and address of the depository;
- (2) The accession number given to the deposit;
- (3) The patent number and issue date of the patent referring to the deposit; and
- (4) The name and address of the requesting party.

Section 1.208: Examination procedures.

(a) The examiner shall determine pursuant to Section 1.104 in each application if a deposit is needed, in case one has not been made, or if a deposit actually made is acceptable for patent purposes. A deposit accepted in any acceptable depository under Section 1.202(a) shall be accepted for patent purposes if made under conditions complying with Section 1.207(a). If a deposit is required and has not been made or replaced in accordance with these regulations, the examiner shall in an Office action reject the affected claims in the application under the appropriate provision of 35 U.S.C. 112, explaining why a deposit actually made cannot be accepted.

(b) The applicant shall respond to a rejection under paragraph (a) of this section by:

- (1) Making an acceptable original or replacement deposit or assuring the Office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee, or
- (2) Establishing that the involved biological material is known and readily available to the public, or

(3) Arguing why a deposit is not required under the circumstances of the application considered. Other replies to the examiner's action shall be considered non-responsive. The rejection will be repeated **until** either paragraph (b)(1) or (b)(2) of this section is satisfied or the examiner is convinced that a deposit is not required.

(c) If an application is otherwise in condition for allowance except for the required deposit and the Office has received a written assurance that an acceptable deposit will be made on or before payment of the issue fee, the Office will mail to the applicant a Notice of Allowance and Issue Fee Due together with a requirement that the required deposit be made within three months. The period for satisfying this requirement is expendable under 37 CFR 1.136. Failure to make the required deposit in accordance with this requirement will result in abandonment of the application for failure to prosecute.

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) Accession number for the deposit;
- (2) Date of the deposit;
- (3) Taxonomic description of the deposit; and
- (4) Name and address of the depository.

SOURCE: U.S. Federal Register, 1988: 53(194), 39420-39432.