

§ 1.808

37 CFR Ch. I (7-1-02 Edition)

(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 § 1.803(a).

§ 1.808 Furnishing of samples.

(a) A 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 § 1.14 and 35 U.S.C. 122, and

(2) Subject to paragraph (b) 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 depositor 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 or other tangible form 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 the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

(c) Upon request made to the Office, the Office will certify whether a 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.

§ 1.809 Examination procedures.

(a) The examiner shall determine pursuant to § 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under the appropriate provision of 35 U.S.C. 112, explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.

(b) The applicant for patent or patent owner shall reply to a rejection under paragraph (a) of this section by—

(1) In the case of an applicant for patent, either making an acceptable original, replacement, or supplemental deposit, or assuring the Office in writing that an acceptable deposit will be made; or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of § 1.805, or

(2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered non-responsive. The rejection will be repeated until either paragraph (b)(1) of

this section is satisfied or the examiner is convinced that a deposit is not needed.

(c) If an application for patent is otherwise in condition for allowance except for a needed deposit and the Office has received a written assurance that an acceptable deposit will be made, applicant will be notified and given a period of time within which the deposit must be made in order to avoid abandonment. This time period is not extendable under § 1.136(a) or (b) if set forth in a "Notice of Allowability" or in an Office action having a mail date on or after the mail date of a "Notice of Allowability" (see § 1.136(c)).

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

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

(e) Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section must be filed before or with the payment of the issue fee (see § 1.312).

[54 FR 34880, Aug. 22, 1989, as amended at 66 FR 21092, Apr. 27, 2001]

APPLICATION DISCLOSURES CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCES

SOURCE: Sections 1.821 through 1.825 appear at 55 FR 18245, May 1, 1990, unless otherwise noted.

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.

(a) Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other

than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2, herein incorporated by reference. (Hereinafter "WIPO Standard ST.25 (1998)"). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of WIPO Standard ST.25 (1998) may be obtained from the World Intellectual Property Organization; 34 chemin des Colombettes; 1211 Geneva 20 Switzerland. Copies of ST.25 may be inspected at the Patent Search Room; Crystal Plaza 3, Lobby Level; 2021 South Clark Place; Arlington, VA 22202. Copies may also be inspected at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC. Nucleotides and amino acids are further defined as follows:

(1) *Nucleotides*: Nucleotides are intended to embrace only those nucleotides that can be represented using the symbols set forth in WIPO Standard ST.25 (1998), Appendix 2, Table 1. Modifications, *e.g.*, methylated bases, may be described as set forth in WIPO Standard ST.25 (1998), Appendix 2, Table 2, but shall not be shown explicitly in the nucleotide sequence.

(2) *Amino acids*: Amino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in WIPO Standard ST.25 (1998), Appendix 2, Table 3. Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition. Any amino acid sequence that contains post-translationally modified amino acids may be described as the amino acid sequence that is initially translated using the symbols shown in WIPO Standard ST.25 (1998), Appendix 2, Table 3 with the modified positions; *e.g.*, hydroxylations or glycosylations, being described as set forth in WIPO Standard ST.25 (1998), Appendix 2, Table 4, but these modifications shall not be shown explicitly in the amino