

§ 1.806

is relied upon during any Office proceeding.

(f) A replacement or supplement deposit made during the pendency of an application for patent may be made for any reason.

(g) In no case is a replacement or supplemental deposit of a biological material necessary where the biological material, in accordance with § 1.802(b), need not be deposited.

(h) No replacement deposit of a biological material is necessary where a depository can furnish samples thereof 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.

(i) The Office will not recognize in any Office proceeding a replacement deposit of a biological material made by a patent owner where the depository could furnish samples of the deposit being replaced.

[54 FR 34880, Aug. 22, 1989, as amended at 62 FR 53202, Oct. 10, 1997]

§ 1.806 Term of deposit.

A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit 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.

§ 1.807 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

37 CFR Ch. I (7-1-08 Edition)

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 depository;

(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 Director 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