§ 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.
§ 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 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 of the deposit;

(3) The date of the viability test; and

(4) A statement that the deposit is capable of reproduction.

§ 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