

## US – UNITED STATES OF AMERICA

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### 1. Requirements for Deposit

The applicant must deposit the biological material with a depositary authority, if the biological material is required to make and use the invention and the biological material is either not known or readily available to the public, or could not have been made or isolated without undue experimentation at the time the invention was made. The depositor may make the required deposit in an international depositary authority recognized under the Budapest Treaty or in a depositary institution recognized by the USPTO and meeting the same requirements.

(37 CFR 1.802 and 1.803; U.S. Patent and Trademark Office, Manual of Patent Examining Procedure, 2001, Sections 2402 and 2404)

### 2. Time of Deposit

The deposit of the biological material must be made by the time the patent issue fee is paid, but the USPTO strongly encourages the deposit to be made on or before the filing date of the application.

(37 CFR 1.804 and 1.809(c); Manual, Sections 2406 and 2411.03)

### 3. Duration of Storage

A deposit must be made for a term of at least 30 years after the date of deposit and at least five years after the most recent request for furnishing a sample of the deposit.

(37 CFR 1.806; Manual, Section 2408)

#### 4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited biological material must be made available to the public at the date of the grant of the patent.

(37 CFR 1.808; Manual, Section 2410.01)

The deposited biological material may be made available during pendency of the patent application which makes reference to the biological material if the person requesting a sample is determined by the USPTO to be entitled thereto. Upon such determination, the Director of the USPTO will make the certification referred to in Rule 11.3(a) of the Regulations under the Budapest Treaty in respect to that person, and will send a copy of the request, together with the certification, to the person who filed the request.

(37 CFR 1.808(a)(1))

(ii) Restrictions Concerning the Furnishing of Samples

Any restriction of public access to samples of deposited biological material must be irrevocably removed as of the date of grant of the relevant patent.

(37 CFR 1.808(a)(2) and Manual, Section 2410.01)