

Overcoming a Rejection for Lack of Written Description or Enablement
by Making a Deposit of Biological Material
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Procedures for Deposition of a Biological Sample to Overcome a 112 Enablement Rejection

According to the Manual of Patent Examining Procedures (MPEP) for the United States Patent and Trademark Office (USPTO), where an invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary to satisfy the requirements for patentability. The courts have also recognized the necessity and desirability of permitting an applicant for patent to supplement the written portion of the application with a deposited sample of biological material that exemplifies the claimed invention to meet patentability requirements. Deposits can be made with any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure, or any other depositary recognized to be suitable by the USPTO.

See <http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/pdf/ida.pdf>.

After finding a suitable depositary for the specific biological material, a deposit can be submitted to the depositary for verification of viability (i.e., replication) and proper storage. A deposit receipt with deposit accession number, a statement of verified viability, and/or a declaration statement regarding the deposited material may be necessary to receive the benefit of the deposit at the USPTO. The specification should also include a reference to the deposited material. While the USPTO does allow biological material to be deposited during examination of a patent application, deposits should be made prior to the filing of the first application, whenever possible, in order to receive the benefit of the deposit in many foreign countries. For more information on the rationale and proper procedures for making a deposit of biological material, please contact the [IP and patent attorneys at Workman Nydegger](#).