

**UNITED STATES  
PATENT AND TRADEMARK OFFICE**





# **Biological Deposits**

## **MPEP 2401-2411 and 37 C.F.R. 1.801-1809**

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# Biological Deposits 37 CFR 1.801-1.809

- Biological deposits may be made in support of the “make and use” requirement of 35 U.S.C. 112(a) when the biological material is not known and readily available.
- A deposit of biological material may be made under the Budapest Treaty or as a non-Budapest Treaty Deposits (US Practice) as set forth in 37 CFR 1.801-1.809.
- 37 CFR 1.801-1.809 addresses procedural matters concerning biological deposits and not substantive issues.
- Both Budapest Treaty and non-Budapest Treaty deposits must provide assurances that:
  - (1) Access to deposited material will be available, during pendency of a patent application making reference to it, to anyone determined by the Director to be entitled to access under 37 CFR 1.14 and 35 U.S.C. 122 (see In re Lundak, 227 USPQ 90, 94-95 (Fed. Cir. 1985) (citing 35 U.S.C. 114)); and
  - (2) Subject to paragraph (b) of 37 CFR 1.808, 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.



# A deposit does not always support enablement

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- Reference to biological material in a specification does not create any presumption that such material is necessary to satisfy 35 U.S.C. 112, or that a deposit in accordance with USPTO rules was required.
- A biological deposit is not considered to be an enabling deposit unless it was made to support enablement and complies with 37 CFR 1.801-1.809!
- A deposit serves to support 35 U.S.C. 112 enablement if it was made to:
  - overcome a rejection under 35 U.S.C. 112.
  - there is, in the record, a statement by the examiner that a rejection would have been made “**but for**” the deposit, or
  - The record otherwise clearly indicates that the deposit was made under the Budapest Treaty, and all restrictions (37 CFR 1.808(b)) imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.



# A deposit does not always support enablement (cont ...)

- Only deposit in an International Depositary Authority (IDA) can support a biological deposit.
- A statement (a declaration is not needed) corroborating the deposit is required.
- Applicants' cannot serve as their own depositary.
- Depositary may be located in any WIPO country.
- In the US only the ATCC, NCMA and NRRL are WIPO IDAs.

# Other 112 issues pertinent to Biological Deposits

- **112(b). Claims that recite a deposit without an accession number**
  - Indefinite for failure to particularly point out and distinctly claim the invention.
  - Example: Seed of the plant of claim 1 having ATCC accession number X.
    - Should be rejected under 112(b) as vague and indefinite.
  - Requirement to claim what the inventor regard as the invention. (In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969))
- **Written description and best mode may arise under 112(a) but rejections under these provisions are seldom made.**
  - WD arises where there is insufficient description to support an amendment.
  - BM arises if the examiner finds that the inventors knew that better specific material existed at the time the application was filed.
  - See MPEP 2411.01 for additional information.

# Budapest Treaty

- The Budapest Treaty is an international agreement (under WIPO) that specifically pertains to the deposit of biological material for the purpose of patent procedure.
- The United States government is a signatory of the Budapest Treaty.
- Deposits made & accepted under the Budapest Treaty are considered to be viable.
- For EPO or JPO patents applications Budapest Treaty deposits must be perfected prior to or on the filing date of the respective applications.
- In contrast to Budapest Treaty deposits in other WIPO member countries, under US practice a deposit made either under the Budapest Treaty or under US practice need not be perfected until the payment of the issue fee.

# Budapest Treaty cont.

- A Budapest Treaty deposit in a US application made after the filing date of the US application is arguable enabling as of the US filing date. The same cannot be said for EPO or JPO applications that depend on the US date.
- Deposit made under the Budapest Treaty require the averment that 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. There are no exceptions to the need for this statement.



# Non-Budapest Treaty Deposits

Non-Budapest Treaty deposits may be perfected at anytime before or at the payment of the issue fee. Non-Budapest Treaty deposits require a viability statement and the following information.

- The name and address of the depositary;
- The name and address of the depositor;
- The date of deposit;
- The identity of the deposit and the accession number given by the depositary;
- The date of the viability test;

# Non-Budapest Treaty Deposits (cont.)

- The procedures used to obtain a sample if the test is not done by the depositary; and
- A statement that the deposit is capable of reproduction.
- A statement of the term of deposit (30 years, or 5 years after the most recent request, or for the enforceable life of the patent, which ever is longer) and that 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.

# Biological Material must be both Known and Readily Available to be Enabling

- A biological material may be known in the sense that its existence has been published, but is not available to those who wish to obtain it.
- Likewise, a biological material may be available in the sense that those having possession of it would make it available upon request, but no one has been informed of its existence.
- The concepts of “known and readily available” are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. (MPEP 2404.01)

# What is Considered Biological Material?

- Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds.
- Viruses, vectors, cell organelles and other “non-living” material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material

# Biological Material Must be Viable and Capable of Self Replication

- Viability does not mean alive in the sense that higher organisms are considered to be “alive.”
- Viability is subject dependent.
- While viability of a “living” cellular organism, such as yeast, can be measured by different means, including metabolic activity, cell division or replication is essential.
- Nucleic acids are considered viable if capable of accurate replication either in a host or independent of the host.
- Similarly, for an infectious virus to be considered viable, indirect replication in an *in vitro* or *in vivo* system would suffice.
- The ability of the virus to act biologically, that is, to produce an infection in a suitable host is not a deposit issue but a broader enablement issue.
- 37 CFR 1.801-1.809 are designed to address procedural matters and not substantive issues.

# When Must A Deposit Be Perfected?

- 37 CFR 1.804.
  - “(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made **at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent.**” (emphasis added)
  - “(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.”
- To obtain a filing date both EPO and JPO require that Biological Deposits be perfected prior to or on the day the application is filed in their respective patent offices.
- Making a deposit with an IDA does not mean that the deposit has been accepted. For example the deposit may fail a viability test and be rejected. Applicants should perfect a deposit as early as possible during prosecution to avoid abandonment for failure to prosecute.

# Reliance on Deposits made by Others

- Biological material deposited in compliance with 37 CFR 1.801-1.809 in order to fulfill statutory requirements may be considered known and readily available upon issuance of the patent.
- An applicant may rely on a deposit of biological material referenced in a patent issued to another **if that deposit is in compliance with the rules.**
  - The examiner will look at the conditions of deposit in the issued patent. If that deposit was not made to satisfy statutory requirements, then the applicant may not rely on it to meet statutory requirements in a pending application.
  - If the examiner cannot determine that the material deposited by “others” is an enabling deposit a rejection should be made under 112(a).

# Supplemental or Replacement Deposits

- If deposited material is inviable or inadequate to meet demand, it may be replaced or supplemented as long as the “new deposit” meets the requirement for the original deposit.
  - A replacement or supplemental deposit must include the filing of a certificate of correction under 37 CFR 1.323.
- If the deposit becomes inviable during prosecution the examiner will treat the application or reexamination proceeding as if **no deposit existed**. (MPEP 2407).
- If the depositary can supply samples of the original material, the Office will not recognize the replacement deposit.



# A Biological Deposit Once Made Cannot Be Withdrawn

- Once a patent issues there is no provision for an applicant to withdraw a deposit from the public when the deposit was made to satisfy the requirements for patentability.
  - Reexamination is not available to address 112 issues.
  - Applicant may file a reissue application.
- If an applicant fails to authorize release of biological material upon the issuance of the patent the party requesting the biological material may seek redress to invalidate the patent.
- An applicant's agreement with an IDA concerning the conditions of deposit is independent from any agreement regarding the deposit of biological material necessary for patentability of an invention.
- Upon issuance the deposit must be made available:
  - All restrictions on the deposit must be irrevocably removed upon issue. The rules do allow for conditions on availability for public health but the applicant must still remove all restriction on availability.

# International Depository Authorities (IDA)

- Only IDAs which are certified by the USPTO or Budapest Treaty Depositaries are acceptable for compliance with statutory requirements in patent applications filed in the United States.
- Deposits for the purpose of satisfying statutory requirements are based on agreements between the USPTO and the applicant, not the IDA.
- IDAs are independent from the USPTO and play no regulatory role in determining compliance with statutory requirements.
- In the US only the ATCC, NCMA and NRRL are IDA's however, patent applicants may use any IDA to support a deposit



# Viability Statement

- The rules do not specify how viability is to be tested. The rules require that the deposited material be capable of self-reproduction either directly or indirectly.
- There is no requirement for a specific percentage or condition of viability.
- The standard applied by the examiner is whether the person skilled in the art would consider the material to be viable.
- There is no requirement for a minimum number of organisms needed to enable a deposit, with one exception.
  - Currently a optimum number of 2500 seeds are required to enable a plant that is reproduced by seed.
- If the examiner, for scientific or other valid reasons, cannot accept the viability statement, the examiner must notify the applicant as to the reasons preventing acceptance. The examiner should process the application as if no deposit had been made.

# American Inventors Protection Act

- AIPA requires that most patent applications be published at 18 months from date of filing.
- These publications are useable as prior art documents for all that they teach.
- Publication means that issue date is no longer the date that the patent disclosure is made public.
- A PGPUB document might not be enabled in the absence of a deposit.
- Keep in mind that:
  - If a deposit had been made prior to publication or issuance, this issue would not arise.
  - The examiner will treat a challenge to the enablement of a PGPUB document being used as a reference carefully because enablement is not determined prior to examination of an application.

# Applicant May Not Act as a Depository

- An applicant cannot function as his or her own IDA and therefore cannot be the depository of biological material necessary to satisfy statutory requirements for patentability.
- An applicant may, however, make biological material necessary to satisfy statutory requirements available by public grant and publication of the material.
- Meeting “known and readily available” by such a mechanism carries no guarantee of unrestricted access to the public. It is possible that at some future time the biological material may become unavailable.
- In the event that biological material becomes unavailable, the invention may no longer satisfy statutory requirements. It is unsettled as to whether this could be corrected by replacement or supplementation via deposit or grant.

# Certification For Release Of Samples of Biological Material Made To Enable An Invention

- Under 37 CFR 1.808(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 depositary;
  - (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.
- The request for certification is made to the USPTO and not the depositary
- The request for certification is not processed by the examiner and must be submitted to the Director of TC 1600.

# A Statement To Corroborate a Deposit Made During Prosecution

- The rules require that an applicant submit a statement from a person in a position to corroborate that the biological material, which is deposited, is a biological material specifically identified in the application.
- A letter from the depositary stating that a deposit has been made and the condition of deposit is not an adequate substitute for a statement made by said person.
- The person capable of making such a statement is decided on a case-by-case basis. Usually an inventor, assignee or attorney having power and being of record is capable making such a statement.

# Application in condition for allowance except for a Deposit

- Under 37 CFR 1.809(c) (see MPEP 2411.03) 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, the Office may notify the applicant in a notice of allowability and set a three month period of time from the mailing date of the notice of allowability within which the deposit must be made in order to avoid abandonment.
- At allowance the examiner will check the box on the PTOL 37
  - “Deposit of and/or Information about the deposit of Biological Material must be submitted. Note the attached Examiner’s comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL”
- The examiner should clearly repeat in the NOA the requirement for a deposit and the timeline including that no extensions are available.



# Application in condition for allowance except for a Deposit (cont.).

- The examiner should not make a Quayle action.
- Once the deposit has been made, information regarding the deposit, such as the name and address of the depository, the accession number and the date of the deposit that is to be added to the specification must be added by means of filing an amendment under the provisions of 37 CFR 1.312.
- Such an amendment must be filed before or with the payment of the issue fee.
- A patent that lacks a necessary deposit is fatally defective for failure to comply with the first paragraph of 35 U.S.C. 112.
- Reissue is not available in such cases. The rules do not provide for post-issuance original deposits.

# Helpful Hints and Tips

- Applicants should perfect a deposit as early as possible during prosecution to avoid abandonment for failure to prosecute.
- If filing US and international patent applications a needed deposit should be deposited and perfected no later than the filing date for the US application.
- Public availability of a deposit made in support of an invention cannot be withdrawn from public availability once a patent issues.
- Under no circumstances will a deposit that has been made in an application in which the biological material is not required for enablement be released to the public.
- Requests for the release of a biological deposit by a third party are made to the issuing Office. Deposits made under the Budapest Treaty are requested using a BP/12 form.
- Although the Budapest Treaty allows for the release of biological material in pending applications and in PCTs the USPTO will only consider a third party requests for a sample of a deposits when a US patent has issued.

# Relevant documents

- MPEP 2402-2411
- 37 CFR 1.801-1.809
- In re Argoudelis, 168 USPQ 99 (CCPA 1970)
- In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969)
- In re Hawkins, 179 USPQ 157 (CCPA 1973)
- In re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985)
- In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988)

