

These rules are equally applicable in the cases of international and national stage applications filed under the Patent Cooperation Treaty. Insofar as the rules do not permit post-issuance original deposits, the failure to make an original deposit in an application cannot be cured by filing a reissue application or instituting a reexamination proceeding. However, if an amendment of claims in a reexamination proceeding raises the need for a deposit, an original deposit may be made during the reexamination proceeding.

2406.01 Description in Application Specification

37 CFR 1.804(a) specifies not only a permissible time frame for making an original deposit, but also specifies that the biological material deposited must be specifically identified in the application for patent as filed. The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. § 112 and provides an antecedent basis for the biological material which either has been or will be deposited before the patent is granted.

The description in the Lundak application as filed (now patent 4,594,325) provides a suitable illustration of the specific identification and description which are required in an application as filed. In that application, an immortal B-cell line was disclosed and claimed. The cell line was referred to in the application, as filed, as WI-L2-729 HF2. The methods of obtaining and using this cell line were also described in the application as filed. A deposit of the cell line was made with the American Type Culture Collection (ATCC) about a week after the application was filed in the United States. The United States Court of Appeals for the Federal Circuit held that the requirements of access by the Office to a sample of the cell line during pendency, and public access after grant, were met by Lundak's procedures. The Court further held that the addition of information designating the depository, accession number, and deposit date of the deposited cell line in ATCC after the filing date did not violate the prohibition against new matter in 35 U.S.C. 132. *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). However, it must be clear from the application as filed that the invention claimed and described in the specification "was fully capable of being reduced to practice (i.e., no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remained in order to obtain an operative, useful process)." *Feldman v. Aunstrup*, 517 F.2d 1351, 1355, 186 USPQ 108, 113 (CCPA 1975), cert. denied, 424 U.S. 912 (1976).

2406.02 Deposit after Filing Date Corroboration

When the original deposit is made after the effective filing date of an application for patent, an applicant is required to promptly submit a verified 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 (the filing date of which is relied upon) as filed. The nature of this corroboration will depend on the circumstances in the particular application under consideration, including the length of time between the application filing date and the date of deposit. While few, if any, situations can be imagined where the description requirement of 35 U.S.C. § 112 can be satisfied where the biological material was not in existence at the time of filing, the rules will not preclude such a situation as there

is no requirement in the patent law that an actual reduction to practice occur as a condition precedent to filing a patent application. The requirement for a verified statement is not necessary under 37 CFR 1.804(b) if the person making the statement is an attorney or agent registered to practice before the Office.

- *under what conditions the amendment of “accession numbers” is permitted;*

Generally speaking, an applicant can amend an application to change an accession number in those situations where it would not introduce new matter into the application. Thus, if, due to a typographical error, an applicant provided an incorrect accession number, it would be possible for that applicant to correct the error provided he or she satisfies the evidentiary proof needed to demonstrate that no new matter is being introduced into the application. Additionally, it is possible for an applicant to amend an application to change or add an accession number in situations where the original deposit of biological material for some reason has not remained viable (i.e., forcing a replacement deposit, and along with that replacement, a possibly new accession number). 37 CFR 1.805 governs the procedures for making replacement or supplementary deposits.

- *whether it is possible to file an application drawn to an invention whose practice can be effected using biological material that has already been deposited by a third party and under which conditions;*

It is possible satisfy the enablement requirements for an invention dependent upon specific biological material through reference to material that has been deposited by a third party. The controlling issue in such a situation remains whether the biological material is “known and publicly available” through the third party deposit.

- *whether access to the deposited biological material is provided or limited after the first publication of the patent application especially when an application is refused or withdrawn;*

This question is not applicable to the United States in view of the fact that applications are not published prior to issuance in the United States.

- *with respect to deposits made in connection with plant inventions, the number of seeds typically required to be provided in a deposit; and*

MPEP Section 2403.02 provides general guidance on the number of seeds that will typically be required incident to a deposit made in support of a utility patent application directed to a plant invention.

As with some types of reproducible biological material, seeds can be reproduced only after a growing season which may be relatively long. Although the rules do not specify a specific number of seeds to be deposited to meet the requirements of these rules, the Office will consider 2500 to be a minimum number in the normal case, but will give an applicant the opportunity to provide justification why a lesser number would be suitable under the circumstances of a particular case. The Department of Agriculture requires a deposit of 2500 seeds for the grant of a Plant Variety Protection Certificate under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.). As the reproduction of seeds will often take a substantial period of time, the Office will require, at a minimum for the grant

of a patent, a number of seeds that is likely to satisfy demand for samples once the patent is granted. In one instance, the Office accepted a deposit of 600 seeds coupled with an undertaking to deposit 1900 more seeds with due diligence. The particular situation involved a "seedless" vegetable with very few seeds per "fruit;" about two growing seasons were required to provide the additional 1900 seeds.

- *whether deposits in other institutions than those listed by the Budapest Treaty are considered, and what requirements are set for such institutions.*

The United States will recognize a depository institution as acceptable if it is either an International Depository Authority (IDA) established under the Budapest Treaty or a depository recognized as suitable by the Commissioner. The conditions that must be met for an institution that has not been recognized as an IDA are specified in 37 CFR 1.803 and in section 2405 of the MPEP, reproduced below.

37 CFR 1.803. Acceptable depository.

- (a) A deposit shall be recognized for the purposes of these regulations if made in
 - (1) any International Depository 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
 - (2) any other depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Commissioner may seek the advice of impartial consultants on the suitability of a depository. The depository must:
 - (i) Have a continuous existence;
 - (ii) Exist independent of the control of the depositor;
 - (iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;
 - (iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;
 - (v) Be impartial and objective;
 - (vi) Furnish samples of the deposited material in an expeditious and proper manner; and

- (vii) Promptly notify depositors of its inability to furnish samples, and the reasons why.
- (b) A depository seeking status under paragraph (a)(2) of this section must direct a communication to the Commissioner which shall:
 - (1) Indicate the name and address of the depository to which the communication relates;
 - (2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (a) (2) of this section, including information on its legal status, scientific standing, staff and facilities;
 - (3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;
 - (4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;
 - (5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a) (2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.
- (c) A depository having status under paragraph (a)(2) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material to the Commissioner in accordance with paragraph (b) of this section. If a previous communication under paragraph (b) of this section is of record, items in common with the previous communication may be incorporated by reference.
- (d) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office. 37 CFR 1.803 indicates that a depository will be recognized as acceptable for the purposes of these regulations if it is either an International Depository Authority (IDA) established under the Budapest Treaty, or if it is a depository recognized as suitable by the Commissioner. After the effective date of these regulations, a deposit of biological material which is made in a depository which is not recognized as acceptable under this regulation will not be considered as satisfying the requirements of 35 U.S.C. § 112. See *Ex parte Humphreys*, 24 USPQ2d 1255 (Bd Pat. App. & Int. 1992). On the other hand, if a deposit is not required to satisfy the requirements of 35 U.S.C. § 112, it is permissible to make reference to such a deposit even though it may not be in a depository or made under the conditions which are acceptable under these regulations. As new depositories are

accepted under the Budapest Treaty or are recognized as suitable by the Commissioner, their identity will be announced in the Official Gazette. An organization may be recognized as suitable by the Office if the procedure and conditions specified in 37 CFR 1.803(a)(2) and 37 CFR 1.803(b) are followed. Generally, it is not the intention of the Office to recognize as suitable any organization where the need for a suitable depository for patent purposes is being met by depositories recognized as IDAs under the Budapest Treaty. Suitability will be judged by the Commissioner, based on need and the information supplied by the organization seeking status, and information obtained from other sources that may be consulted. While there is a desire to provide flexibility to a patent applicant in selecting an appropriate depository, these rules are not intended to permit each patent applicant to become its own depository since both the patent owner and the public have an interest in the continued availability and accessibility of the deposit during the enforceable life of the patent, and the public has a continuing interest in its availability when the patent is no longer enforceable. The concept of a depository independent of the control of the depositor or an IDA as an acceptable depository is based on the need and desire to ensure the safe and reliable storage of a deposited biological material under circumstances that are substantially free of the opportunity for intentional mishandling or negligent handling of the deposited material. The use of an independent depository or internationally recognized depository will tend to preserve the integrity of the deposit process against those that may accidentally alter the deposited material, may wish to tamper with the deposited material or may wish to resume control of its availability when the patent is no longer enforceable, and will tend to preserve the interest of the public in the access to the biological material once the term of the patent expires.

When a depository having status under 37 CFR 1.803(a)(2) seeks to change the kinds of biological materials that it will accept and maintain for the purposes of these rules, a communication requesting such a change should be directed to the Commissioner containing the information requested in 37 CFR 1.803(b). When such a change is requested, the requesting depository should provide a complete list of the kinds of biological materials it will accept. 37 CFR 1.803(d) indicates that once a depository is recognized as suitable for the purposes of this rule, or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office. A current list (as of January, 1993) of IDAs recognized under the Budapest Treaty, with addresses, is included below. The mere fact that a deposit has been made in one of these depositories does not mean that the terms of the deposit meet either the requirements of the Budapest Treaty or the deposit regulations. Many of the depositories recognized under the Budapest Treaty have many different arrangements under which biological material may be stored.

The World Intellectual Property Organization (WIPO) publishes a Guide to the Deposit of Micro-organisms under the Budapest Treaty (WIPO