available" is considered appropriate to define that degree of availability which would be reasonable under the circumstances. If the biological material and its natural location can be adequately described so that one skilled in the art could obtain it using ordinary skill in the art, the disclosure would appear to be sufficient to meet the enablement requirement of 35 U.S.C. § 112 without a deposit so long as its degree of availability is reasonable under the circumstances.

By showing that a biological material is known and readily available or by making a deposit in accordance with these rules, applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of a deposited biological material during and after the period of enforceability of the patent, there should not be any undue concern about continued access to the public. Unless there is a reasonable basis to believe that the biological material will cease to be available during the enforceable life of the patent, current availability would satisfy the requirement. The incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. In re Metcalfe, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969). If an applicant has adequately established that a biological material is known and readily available, the Office will accept that showing. In those instances, however, the applicant takes the risk that the material may cease to be known and readily available. Such a defect cannot be cured by reissue after the grant of a patent.

On the other hand, Ex parte Humphreys, 24 USPQ2d 1255 (Bd Pat. App. & Int. 1992), held that the only manner in which applicants could satisfy their burden of assuring public access to the needed biological material, and, thereby, compliance with the enablement requirement of 35 U.S.C. § 112, was by making an appropriate deposit. The fact that applicants and other members of the public were able to obtain the material in question from a given depository prior to and after the filing date of the application in issue did not establish that upon issuance of a patent on the application that such material would continue to be accessible to the public. The applicants did not make of record any of the facts and circumstances surrounding their access to the material in issue from the depository, nor was there any evidence as to the depository's policy regarding the material if a patent would have been granted. Further, there was no assurance that the depository would have allowed unlimited access to the material if the application had matured into a patent.

There are many factors that may be used as indicia that a biological material is known and readily available to the public. Relevant factors include commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, evidence of predictable isolation techniques, or an existing deposit made in accordance with these rules. Each factor may or may not be sufficient alone to demonstrate that the biological material is known and readily available. Those applicants that rely on evidence of accessibility other than a deposit take the risk that the patent may no longer be enforceable if the biological material necessary to satisfy the requirements of 35 U.S.C. § 112 ceases to be accessible. The Office will accept commercial availability as evidence that a biological material is known and readily available only when the evidence is clear and convincing that the public has access to the material. A product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample. The relationship between the

applicant relying on a biological material and the commercial supplier is one factor that would be considered in determining whether the biological material was known and readily available. However, the mere fact that the biological material is commercially available only through the patent holder or the patent holder's agents or assigns shall not, by itself, justify a finding that the necessary material is not readily available, absent reason to believe that access to the biological material would later be improperly restricted.

The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception, that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd Pat. App. & Int. 1990).

A Budapest Treaty deposit cited in a U.S. patent need not be made available if it was not required to satisfy 35 U.S.C. § 112. Thus, a reference to a deposit will not be certified available unless either (1) the deposit was necessary to overcome a rejection under 35 U.S.C. § 112, or (2) there is, in the record, a statement by the examiner that a rejection under 35 U.S.C. § 112 would have been made "but for" the deposit (assumes deposit information in record, as filed). Otherwise, public access cannot be certified and the deposit cannot be relied upon for other purposes, e.g., the deposit cannot be relied upon by a third party to establish "known" and "readily available" in another application. See 37 CFR 1.808 and MPEP w 2410 and 2410.02.

Once a deposit is made in a depository complying with these rules, and under conditions complying with these rules, a biological material will be considered to be readily available even though some requirement of law or regulation in the United States or in the country where the depository institution is located permits access to the material only under conditions imposed for health, safety or similar reasons. This provision is consistent with the Budapest Treaty (Article 5) and is designed to permit the patenting of inventions involving materials having restricted distribution, where the restrictions are imposed for the public, as opposed to the private, welfare.

2404.02 - Biological Material that Can be Made or Isolated Without Undue Experimentation

Applicant may show that a deposit is not necessary even though specific biological materials are required to practice the invention if those biological materials can be made or isolated without undue experimentation. Deposits may be required to support the claims if an isolation procedure requires undue experimentation to obtain the desired biological material. *Ex parte Jackson*, 217 USPQ 804 (Bd App. 1982). No deposit is required, however, where the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test. *Tabuchi v. Nubel*, 559 F.2d 1183, 194 USPQ 521 (CCPA 1977); *Ex parte Hata*, 6 USPQ 2d 1652 (Bd Pat. App. & Int. 1987).

*In addition , please indicate:*

- *whether the deposit of biological material can be required, and if so, under what conditions;*

As explained above, the PTO can require that an applicant provide evidence that he or she has deposited a sample of biological material in conformity with the requirements for deposits of microorganisms (37 CFR 1.801 et seq.) where such a deposit would be necessary to enable one skilled in the art to practice the invention without undue experimentation.

- *whether an applicant can satisfy enablement requirements other than through a deposit of a sample with a recognised institution (e.g. through reference to morphological or other written descriptions or a clause assuring access from the applicant); and*

In certain situations, an applicant can satisfy the enablement requirement for claims directed to specific biological material or to an invention dependent upon specific biological material through a description of the material, rather than deposit of a sample of the microorganism. For example, if one skilled in the art can use a description of the morphological characteristics of the organism, coupled with information as to where one could obtain the microorganism, it may be possible to enable a claim to the microorganism through reliance on the written description. See also, MPEP 2404.01.

- *the nature of materials (e.g. genes, plasmids, cells, zygotes, tissue samples, living organisms) that have been recognised as appropriate forms of deposits.*

The nature of materials that can be the subject matter of a deposit are defined in 37 CFR 1.801. The rules use the generic term "biological material" to encompass any form of material that is capable of self-replication, either directly or indirectly. Section 1.801 includes a representative list of materials that fall within the definition of biological material, namely: "bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds." The rules also permit the deposit of living material that will permit the production of material that itself is not capable of self-replication; thus, section 1.801 enables the deposit of viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell through a deposit of a host cell capable of reproducing the non-living material.

*(ii) As regards the deposits made in the context of a patent procedure, please indicate:*

- *whether deposit after filing is allowed;*

Under US law, an applicant can deposit a sample of a microorganism that would be necessary to support enablement of an application after the application has been filed. Two requirements must be met, however, in such situations. First, the biological material must be specifically identified in the application for patent as filed (see, 37 CFR 1.804(a)). Second, the applicant must provide corroboration that demonstrates that the biological material that has been deposited is a biological material specifically identified in the application as filed. These two requirements serve to ensure that (a) the written description requirement of 35 U.S.C. § 112 is satisfied, and (b) that no new matter is

being added to the disclosure pursuant to the act of depositing and identifying the deposit of biological material. The PTO thus permits, but does not recommend that, an applicant to make a deposit after the application has been filed.

The time of deposit is governed by 37 CFR 1.804 and 1.809. Section 1.804 provides:

> 37 CFR 1.804 Time of making an original deposit.
>
> (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.
>
> (b) When the original deposit is made after the effective filing date of an application for patent, the applicant shall promptly submit a verified statement from a person in a position to corroborate the fact, and shall state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified.

Section 1.809 explains the examination procedures that govern situations in which a deposit is required but has not been made by the applicant at the time of original filing.

> 37 CFR 1.809 Examination procedures.
>
> (a) The examiner shall determine pursuant tow 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 respond to a rejection under paragraph (a) of this section by —
>
> (1) In the case of an applicant for patent, making an acceptable original or replacement or supplemental deposit or assuring the Office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee, 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 nonresponsive. The rejection will be repeated until either paragraph (b)(1) of this section is satisfied or the examiner is convinced that a deposit is not needed.

(c) 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 on or before payment of the issue fee, the Office will mail to the applicant a Notice of Allowance and Issue Fee Due together with a requirement that the needed deposit be made within three months. The period for satisfying this requirement is extendable under § 1.136. Failure to make the needed deposit in accordance with this requirement will result in abandonment of the application for failure to prosecute.

(d) For each deposit made pursuant to these regulations, the specification shall contain:

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

A complete description of issues relating to deposits made after the original filing date of an application is provided in sections 2406.01 and 2406.02 of the MPEP, reproduced below.

2406 Time of Making an Original Deposit

37 CFR 1.804 specifies the time for making an original deposit to fulfill the requirements of 35 U.S.C. § 112. For the reasons discussed throughout this section, it is recommended that a deposit be made before the filing date of the application. However, for the purposes of complying with the requirements of 35 U.S.C. § 112, a deposit of a biological material may be made at any time before filing the application for patent or during the pendency of the application subject to the conditions of 37 CFR 1.809. Where a deposit is needed to satisfy the requirements of 35 U.S.C. § 112 and it is made during the pendency of the application, it must be made no later than the time period set by the examiner at the time the Notice of Allowance and Issue Fee Due is mailed. A necessary deposit need not be made by an applicant until the application is in condition for allowance so long as the applicant provides a written assurance that an acceptable deposit will be made on or before the payment of the issue fee. This written assurance must provide sufficiently detailed information to convince the examiner that there is no outstanding issue regarding deposits that needs to be resolved.