3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Deposit of Biological Materials

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on November 22, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Deposit of Biological Materials.

OMB Control Number: 0651-0022.

Needs and Uses: This collection covers information from patent applicants who seek to deposit biological materials as part of a patent application according to 37 CFR 1.801-1.809. The information collected from such patent applicants consists of information and documentation demonstrating the applicant's compliance with regulatory requirements, as well as information regarding the biological sample after it is deposited. This collection also covers applications from institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent

application purposes. The information collection requirements for these actions are separate, as further discussed below.

A. Deposits of Biological Materials

The deposit of biological materials as part of a patent application is authorized by 35 U.S.C. 2(b)(2). The term "biological material" is defined in 37 CFR § 1.801 as including material that is capable of self-replication, either directly or indirectly. When an invention involves a biological material, words and figures may not sufficiently describe how to make and use the invention in a reproducible manner as required by 35 U.S.C. 112. In such cases, the inventive biological material must be known and readily available to the public or can be made or isolated without undue experimentation (see 37 CFR § 1.802). In order to satisfy the "known and readily available" requirement, the biological material may be deposited in a suitable depository that has been recognized as an International Depositary Authority (IDA) established under the Budapest Treaty per 37 CFR § 1.803(a)(1), or any other depository recognized to be suitable by the USPTO per 37 CFR § 1.803(a)(2). Under the authority of 35 U.S.C. section 2(b)(2), the deposit rules (37 CFR §§ 1.801–1.809) set forth examining procedures and conditions of deposit which must be satisfied in the event a deposit is required.

In cases where a deposit of biological material that is capable of self-replication either directly or indirectly is made, and the deposit is not made under the Budapest Treaty, the USPTO collects information to determine whether the deposit meets the viability requirements of 37 CFR § 1.807. This information includes a viability statement under 37 CFR § 1.807, such statement identifying:

(1) The name and address of the depository where the deposit was made;

(2) The name and address of the depositor;

(3) The date of the deposit;

(4) The identity of the deposit and the accession number given by the depository;

(5) The date of the viability test;

(6) The procedures used to obtain a sample if the test was not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

A viability statement is not required when a deposit is made and accepted under the Budapest Treaty.

This collection also covers additional information that may be gathered by the USPTO after a biological material is deposited into the recognized depository. For example, depositors may be required to submit verification statements for biological materials deposited after the effective filing date of a patent application or written notification that an acceptable deposit will be made. Occasionally a deposit may be lost, contaminated, or is not able to self-replicate, and a replacement or supplemental deposit needs to be made. This information collection includes a required written notification that the depositor must submit to the USPTO disclosing the particulars of such situation and request a certificate of correction by the USPTO authorizing a replacement or supplemental deposit.

There are no forms associated with the information collected by the USPTO in connection with the deposit of biological materials, however there are forms available under the Budapest Treaty for use with international depositories.

B. Depositories

Institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes, are required by 37 CFR § 1.803(b) to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications (see also MPEP 2405). This collection covers the information that a depository must submit to the USPTO when seeking recognition by the Office as a suitable depository under 37 CFR § 1.803(a)(2). This

information enables the USPTO to evaluate whether such a depository has internal practices (both technical and administrative) and the technical ability sufficient to protect the integrity of the biological materials being stored by U.S. patent applicants. This information includes:

(1) The name and address of the depository seeking recognition under 37 CFR § 1.803(a)(2),

(2) Detailed information as to the capacity of the depository to comply with the requirements of 37 CFR § 1.803(a)(2), including information on its legal status, scientific standing, staff, and facilities;

(3) An indication 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; and

(5) An indication of 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.

This collection also includes additional information gathered by the USPTO that may be needed after a depository has been recognized by the USPTO under 37 CFR § 1.803(a)(2), such as requests to handle additional types of biological materials other than the material originally recognized, and viability statements that depositories may submit on behalf of depositors for deposits tested at the depository and/or documentation proving the public has been notified about where to obtain samples. There is no application form associated with requests under 37 CFR § 1.803(b) to become a recognized depository.

Form Number(s): No form associated for domestic depositories; Forms BP/1, BP/2, BP/3, BP/9 for use of international depositories under the Budapest Treaty.

- BP/1 (Statement in the Case of an Original Deposit (Rule 6.1)).
- BP/2 (Statement in the Case of a New Deposit with the Same International Depositary Authority (Rule 6.2)).
- BP/3 (Statement in the Case of a New Deposit with Another International Depositary Authority (Rule 6.2)).
- BP/9 (Viability Statement (Rule 10.2) (International Form)).

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 3,301 respondents.

Estimated Number of Annual Responses: 3,301 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately between 1 hour and 5 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 3,305 hours.

Estimated Total Annual Respondent Non-Hourly Cost Burden: $9,259,809.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Commerce, USPTO information collections currently under review by OMB.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by

selecting ‘‘Currently under 30-day Review—Open for Public Comments’’ or by using the search function and entering either the title of the information collection or the OMB Control Number 0651–0022.

Further information can be obtained by:

- E-mail: InformationCollection@uspto.gov. Include “0651-0022 information request” in the subject line of the message.
- Mail: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Justin Isaac,

Information Collections Officer,

Office of the Chief Administrative Officer,

United States Patent and Trademark Office.

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