3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

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

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

ACTION: Notice of information collection; request for comments.

SUMMARY: The United States Patent and Trademark Office (hereafter "USPTO" or "Agency"), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0022 (Deposit of Biological Materials). The purpose of this notice is to allow 60 days for public comments preceding submission of the information collection to the Office of Management and Budget (OMB).

DATES: To ensure consideration, you must submit comments regarding this information collection on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- Email: InformationCollection@uspto.gov. Include "0651-0022 comment" in the subject line of the message.
- Federal eRulemaking Portal: http://www.regulations.gov.

- Mail: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.
- Telephone: Raul Tamayo, Senior Legal Advisor, 571-272-7728.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor at: Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; 571-272-7728; or raul.tamayo@uspto.gov with "0651-0022 comment" in the subject line. Additional information about this information collection is also available at http://www.reginfo.gov under "Information Collection Review."

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection covers information from patent applicants who seek to deposit biological material for patent purposes 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 discussed below.

A. Deposits of Biological Material

The deposit of biological material for patent purposes is authorized by 35 U.S.C. 2(b)(2). The term "biological material" is defined in § 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 be

capable to be made or isolated without undue experimentation (see § 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 Depository Authority (IDA) established under the Budapest Treaty per § 1.803(a)(1), or any other depository recognized to be suitable by the USPTO per § 1.803(a)(2). Under the authority of 35 U.S.C. 2(b)(2), the deposit rules (§§ 1.801-1.809) set forth the examination 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 § 1.807. This information includes a viability statement under § 1.807 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 procedure 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 information 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 material deposited after the effective filing date of a patent application, or written notification that an acceptable deposit will be made. As another example, occasionally a deposit may become lost, contaminated, or incapable of functioning as described in the specification, and a replacement or supplemental deposit needs to be made. This information collection includes the written notification that the depositor must submit to the USPTO disclosing the particulars of the need for a replacement or supplemental deposit, as well as the request for certificate of correction that is required when the replacement or supplemental deposit is being made in connection with a patent.

The USPTO does not provide forms for the information it collects in connection with the deposit of biological material. The International Bureau of the World Intellectual Property Organization provides forms for the deposit of biological material at an IDA under the Budapest Treaty.

B. Depositories

Institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes are required by § 1.803(b) to make a request demonstrating that they are qualified to store and test the biological material submitted to them under patent applications (see also MPEP 2405). This information collection covers the information that a depository must submit when seeking recognition by the USPTO as a suitable depository under § 1.803(a)(2). Depositories should comply with the requirements of § 1.803(b) when requesting to become a recognized depository.

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 material being stored by U.S. patent applicants. The information that the depository provides includes:

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

(2) Detailed information as to the capacity of the depository to comply with the requirements of § 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, such kinds must be specified; and

(5) An indication of the amount of any fees that the depository will, upon acquiring the status of a suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of the 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 § 1.803(a)(2). This information could include requests to handle additional types of biological material other than the material originally recognized, viability statements that depositories may submit on behalf of depositors for deposits tested at the depository, and documentation that the public has been notified about where to obtain samples.

II. Method of Collection

Items in this information collection may be submitted electronically. Applicants may also submit the information in paper form by mail, fax, or hand delivery.

III. Data

OMB Control Number: 0651-0022.

Forms: (BP = Budapest)

- 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 Depository Authority (Rule 6.2))

- BP/3 (Statement in the Case of a New Deposit with Another International Depository 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: 1,501 respondents.

Estimated Number of Annual Responses: 1,501 responses.

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

Estimated Total Annual Respondent Burden Hours: 1,505 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $672,735.

Table 1: Total Reporting Burden Hours and Hourly Costs to Private Sector Respondents

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time for Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate[1] ($/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Deposited Materials	1,500	1	1,500	1	1,500	$447	$670,500
2	Request for Depository Approval	1	1	1	5	5	$447	$2,235
	Totals	**1,501**	**- - -**	**1,501**	**- - -**	**1,505**	**- - -**	**$672,735**

[1] 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association, pg. F-41. The USPTO uses the average billing rate for intellectual property work in all firms, which is $447 per hour (www.aipla.org/home/news-publications/economic-survey).

Estimated Total Annual Respondent Non-hourly Cost Burden: $4,306,511. There are no maintenance costs, recordkeeping costs, or filing fees associated with this information collection. However, the USPTO estimates that the total annual non-hour cost burden for this information collection, in the form of capital start-up costs and postage, is $4,306,511.

Capital Start-Up Costs

Depositories charge fees to depositors, and all depositories charge about the same rates for their services. For example, the American Type Culture Collection (ATCC), one of the world's leading biological supply houses and recognized patent depositories, offers comprehensive patent services for $2,500 per deposit.[2] Any deposit made from outside the U.S. may have additional requirements from other federal agencies as part of their importation process. For the purposes of this information collection, the USPTO estimates that the depository fee is $2,500 per deposit. The breakout for these costs is listed in the table below.

Table 2: Capital Start Up Costs

Item No.	Item	Estimated Annual Responses (a)	Filing Fee ($) (b)	Non-hourly Cost Burden (a) x (b) = (c)
1	Deposited Material Depository Fee	1,500	$2,500	$3,750,000
	Totals	**1,500**	**- - -**	**$3,750,000**

Postage Costs

Biological deposits are generally shipped to the depository "Domestic Overnight" by Federal Express (FedEx). Since depositors are urged to supply frozen or freeze-dried materials, it must be packed in dry ice. Dry ice itself is considered a dangerous good and requires special packaging. Additional FedEx special handling charges for inaccessible

[2] The ATCC Patent Depository service fee is $2,500 per deposit, which is incurred at the time of receipt of a portion or all of the materials (https://www.atcc.org/services/depositing-with-atcc/patent-deposit).

dangerous goods shipments is $73 per shipment,[3] which applies to temperature-sensitive biological materials and dry ice.

An average cost for shipping by FedEx "Domestic Overnight" can vary depending on the size of the package, the delivery time, and the delivery distance. For purposes of this information collection, the USPTO estimates that the FedEx Domestic Overnight charge for a biological deposit is $120 per shipment. If the shipment requires a pick-up by FedEx, there is an additional charge of $7.50.[4] Special packaging is also required for these shipments. The average cost of frozen infectious shipments is estimated to be $170 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, the USPTO estimates that the total average postage cost is $371 per shipment. The USPTO estimates that respondents to this information collection will ship 1,500 biological deposits, for a total of $556,500. The USPTO estimate that it will receive 1 depository request for recognition. The USPTO estimates that the postage cost for this type of mailed submission, using a Priority Mail legal flat-rate envelope, will be $11.20. Combining these rates, the USPTO therefore estimates that the total mailing costs for this information collection is $556,511 per year.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

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[3] FedEx, How to Ship Dangerous Goods (https://www.fedex.com/en-us/service-guide/dangerous-goods/how-to-ship.html).

[4] FedEx, U.S. Parcel Pickup Options (https://www.fedex.com/content/dam/fedex-com/hdn/FedEx-US-Pickup-Options-with-rates-2025.pdf).

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information for those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. The USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be advised that the entire comment—including PII—may be made publicly available at any time. While you may request to withhold PII from public view, the USPTO cannot guarantee that it will be able to do so.

Justin Isaac,
Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

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