SUPPORTING STATEMENT
United States Patent and Trademark Office
Deposit of Biological Materials
OMB CONTROL NUMBER 0651-0022
(November 2013)

A. JUSTIFICATION

This supporting statement covers both deposits of biological materials and the depositories in which they are stored. While these two topics are related, the information collection requirements for a respondent depositing biological material are not the same as those that must be followed by a respondent seeking approval from the United States Patent and Trademark Office (USPTO) to store biological materials. These different requirements are addressed in separate sections. Section 1.a. deals with the deposit of biological materials and section 1.b. deals with the depositories. There are no forms associated with this collection.

1. Necessity of Information Collection

a. Deposited Materials

The deposit of biological materials as part of a patent application is authorized by 35 U.S.C. § 2(b)(2) and required by 37 CFR 1.801-1.809. Every patent must contain a written description of the invention sufficient to enable a person (of ordinary skill in the relevant art) to make and use the invention as specified by 35 U.S.C. § 112. 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, sometimes words and figures are not sufficient to satisfy the statutory requirement for patentability under 35 U.S.C. § 112. In such cases, the required biological material must either be: (1) known and readily available (neither condition alone is sufficient) or (2) deposited in a suitable depository that has been recognized as an International Depositary Authority (IDA) established under the Budapest Treaty, or a depository recognized by the USPTO to meet the requirements of 35 U.S.C. § 112. Under the authority of 35 U.S.C. § 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. The rules do not address the substantive issue of whether a deposit is required under any particular set of facts.

In cases where a deposit is necessary, it must be made under conditions that assure that: (i) access to the deposit will be available to those entitled thereto under 35 U.S.C. § 122 and 37 CFR 1.14, and (ii) all restrictions to public access will be irrevocably removed upon the granting of the patent.

In cases where a deposit is necessary, the USPTO collects information to determine whether the depositor is in compliance with the deposit rules. This includes statements proving notification to the interested public on where to obtain samples of the deposits

and confirming that all restriction on access to the deposit will be irrevocably removed upon issuance of the patent.

A viability statement must also be submitted to the USPTO showing that the biological material was tested by the depository or another, the conditions of the test, and that it is a viable or acceptable deposit. In particular, a viability statement may be provided in one of two ways:

(1) If a deposit is made that is acceptable under the Budapest Treat, then a mere statement by an applicant, an authorized representative of applicant or the assignee that the deposit has been accepted under the Budapest Treaty would satisfy as a viability statement under 37 CFR 1.807; or

(2) If a deposit is not made to a facility that is registered under the Budapest Treaty, then a viability statement with the following information must be provided (see 37 CFR 1.807(b)):

- The name and address of the depository;
- The name and address of the depositor;
- The date of deposit;
- The identity of the deposit and the accession number given by the depository;
- The date of the viability test;
- The procedures used to obtain a sample if the test is not done by the depository; and
- A statement that the deposit is capable of reproduction.

Once a depositor has deposited biological materials into a recognized depository, occasions may arise necessitating additional communication between the depositor and the USPTO. 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 otherwise cannot function as described in the patent application, and a replacement or supplemental deposit needs to be made. In that event, the depositor must submit a written notification to the USPTO concerning the particulars of the situation and request a certificate of correction by the USPTO authorizing the replacement or supplemental deposit.

A deposit made before or during the pendency of an application will be kept for a term of at least 30 years, and for at least five years after the most recent request for the furnishing of a sample of the deposit was received by the depository. Samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

In order to meet and satisfy requirements for international patenting, all countries signing the Budapest Treaty must recognize the deposit of biological material with any International Depositary Authority (IDA).

To summarize, the nature of the information collected by the USPTO in association with the deposit of biological materials is that of certifications/statements, as described above, regarding a biological sample deposited at a depository. There is no form associated with the information collected by the USPTO in connection with the deposit of biological materials.

b. Request for Depository Approval

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 to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications. A depository seeking recognition from the USPTO to store biological materials must show that internal practices (both technical and administrative) and the technical ability of the staff and the facility are sufficient to protect the integrity of the biological materials being stored. In particular, 37 CFR 1.803 requires the institution to direct a communication to the USPTO Director that shall:

- indicate the name and address of the depository to which the communication relates;
- contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (a)(2) of 37 CFR 1.803, including information on its legal status, scientific standing, staff, and facilities;
- indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;
- where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds; and
- indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of 37 CFR 1.803, charge for storage, viability statements and furnishings of samples of the deposit.

USPTO rules are stringent to ensure the competence and quality of depositories. Depositories granted USPTO recognition must be established institutions with a long-standing reputation and recognized by their peers for the quality of their work. The depository must have a continuous existence, exist independent of the control of the depositor, and be impartial and objective. The USPTO determines the suitability of a depository based on its administrative and technical competence, and its agreement to comply with the requirements in this rule concerning the deposit of biological materials. Depositories must submit documentation to the USPTO that verifies that their practices and procedures, the technical competence of their staff, and their facilities fulfill the stringent requirements spelled out under the rules.

Once a depository has been recognized by the USPTO, occasions may arise where additional communication between the depository and the USPTO is necessary. For

example, a depository must request and obtain written approval from the USPTO to handle additional types of biological materials other than the material originally recognized. Depositories may (on behalf of depositors) submit viability statements for deposits tested at the depository and/or documentation proving the public has been notified about where to obtain samples.

Communication between the depository and the public occurs when the public requests a sample of a biological material deposited in the depository. Depositories also notify the depositors in writing whenever a sample is furnished.

Once a depository is recognized to be suitable by the USPTO, or has defaulted or discontinued its performance, notice thereof is required to be published in the *Official Gazette of the United States Patent and Trademark Office*.

To summarize, the nature of the information collected by the USPTO in connection with a respondent seeking approval from the USPTO to store biological materials is that of a written request to the Director of the USPTO containing the information outlined above. There is no form for the request.

2. Needs and Uses

This information is used by the USPTO to determine whether the applicant has met the requirements of the patent regulations regarding deposits of biological materials. The USPTO also uses the information to determine the suitability of a respondent depository based upon administrative and technical competence and the depository's agreement to comply with the requirements set forth by the USPTO.

The Information Quality Guidelines from Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for fiscal year 2001, apply to this information collection, and this information collection and its supporting statement comply with all applicable information quality guidelines, *i.e.* OMB and specific operating unit guidelines.

Table 1 provides the specific statutes and rules requiring the USPTO to collect the information discussed above and how this information is used by the public and the USPTO.

Table 1: Information Requirements and Needs and Uses of Information Collected

Item #	Requirement	Statute	Rule	Form #	Needs and Uses
1	Deposited Materials -Samples -Certification/Viability Statements	35 U.S.C. § 2(b)(2), 35 U.S.C. § 112	37 CFR 1.801-1.809, 37 CFR 1.14	No Form	• Used by an applicant to determine whether to file a new patent application. • Used by an applicant to establish enablement of claimed biological material. • Used by an applicant to establish possession of the invention for priority purposes. • Used by an applicant to maintain

Item #	Requirement	Statute	Rule	Form #	Needs and Uses
					enforceability of a patent. • Used by the USPTO to determine whether the requirement of 35 U.S.C. § 112, 1st paragraph, have been met. • Used by the USPTO to determine whether the depositor is in compliance with deposit rules.
2	Request for Depository Approval	35 U.S.C. § 2(b)(2)	37 CFR 1.803	No Form	• Used by the respondent depositories to determine the requirements that they must follow in order to be recognized by the USPTO as a suitable depository. • Used by recognized depositories to justify their recognition and to ensure that they remain in compliance administratively and technically, that they hire qualified staff, and that their facilities are suitably equipped for the storage and testing of deposits of biological material. • Used by the USPTO to determine suitability of a respondent depository based upon administrative and technical competence and the depository's agreement to comply with the requirements set forth by the USPTO.

3. Use of Information Technology

Currently, the USPTO does not use automated, electronic, mechanical, or other technological collection techniques for this collection. As the USPTO expands electronic filing under the Electronic Filing System (EFS-Web), the Deposit of Biological Materials Program will be evaluated to determine whether electronic filing is feasible. The deposit of the physical specimen itself cannot be done electronically. If the USPTO determines that electronic filing of the documentation from depositories seeking consideration as an acceptable depository is both feasible and practicable, it will submit the electronic form or template to OMB for review.

4. Efforts to Identify Duplication

This information is collected during the prosecution of a patent application containing biological materials. It is not collected elsewhere. Therefore, this collection does not create a duplication of effort.

5. Minimizing the Burden to Small Entities

This collection of information does not impose a significant economic impact on small entities or small businesses. The same information is required of every applicant and is not available from any other source.

6. Consequences of Less Frequent Collection

This information is collected only when the respondent submits a patent application containing biological materials that cannot be adequately described in words only or when a depository seeks consideration as an acceptable depository. It could not be conducted less frequently. If the collection of information were not collected, the USPTO could not comply with the requirements of 35 U.S.C. § 2(b)(2) and 37 CFR 1.801-1.809.

7. Special Circumstances in the Conduct of Information Collection

There are no special circumstances associated with this collection of information.

8. Consultations Outside the Agency

The 60-Day Notice was published in the *Federal Register* on March 15, 2013 (78 Fed. Reg. 16472). The comment period ended on May 14, 2013. No public comments were received.

The USPTO has long-standing relationships with groups from whom patent application data is collected, such as the American Intellectual Property Law Association (AIPLA), as well as patent bar associations, independent inventor groups, and users of our public facilities. Views expressed by these groups are considered in developing proposals for information collection requirements.

9. Payment or Gifts to Respondents

This information collection does not involve a payment or gift to any respondent.

10. Assurance of Confidentiality

Confidentiality of patent applications is governed by statute (35 U.S.C. § 122) and regulation (37 CFR 1.11 and 1.14). The USPTO has a legal obligation to maintain the confidentiality of the contents of unpublished patent applications and related documents. Upon publication of an application or issuance of a patent, the patent application file is made available to the public, subject to the provisions for providing only a redacted copy of the file contents.

11. Justification for Sensitive Questions

None of the required information in this collection is considered to be sensitive.

12. Estimate of Hour and Cost Burden to Respondents

For clarity, the burden explanations have been separated into sections a. and b. Table 2 combines both the deposits of biological materials and the depositories' information

and calculates the burden hours and costs of this information collection to the public, based on the following factors:

a. Deposited Materials

- **Respondent Calculation Factors**
  The USPTO estimates that approximately 2,000 deposits of biological materials are made per year in order to meet the requirements of 35 U.S.C. § 112 for inventions pertaining to biological materials, with 5% of these from small entities.

  These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected by these items.

- **Burden Hour Calculation Factors**
  The USPTO estimates that the burden hours required by the average patent applicant respondent to collect and submit the necessary deposit information would be 1 hour annually.

  These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected and the length of time necessary to complete responses containing similar information.

- **Cost Burden Calculation Factors**
  The USPTO expects that a senior administrative assistant, at a rate of $30 per hour, would prepare this information.

b. Request for Depository Approval

- **Respondent Calculation Factors**
  No depository has requested recognition by the USPTO to serve as a depository of biological materials since September 1994. Five existing depositories were grandfathered under current law in 1994. For the purpose of this submission, the USPTO estimates that one depository might seek recognition every four years, rounded up to 1 response annually.

  These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected by these items.

- **Burden Hour Calculation Factors**
  The USPTO estimates that the burden hours required by the average depository seeking approval to store biological materials would be approximately 5 hours spent in collecting and submitting the necessary approval information. This is the historical estimate for this collection. The agency has not received any public comment to the contrary and maintains the estimate.

  These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected and the length of time necessary to complete responses containing similar information.

- **Cost Burden Calculation Factors**
  The USPTO uses a professional rate of $371 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the 2011 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA).

Table 2: Burden Hour/Burden Cost to Respondents

Item #	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/hr) (e) (c) x (d)
1	Deposited Materials -Samples -Certification/Viability Statements	1.0	2,000	2,000	$30.00	$60,000.00
2	Request for Depository Approval	5.0	1	5	$371.00	$1,855.00
	Total	**- - - - -**	**2,001**	**2,005**	**- - - -**	**$61,855.00**

13. Total Annualized (Non-hour) Cost Burden

There are no maintenance costs, record keeping costs, or filing fees associated with this information collection. There are, however, capital start-up and postage costs.

Depositories charge fees to depositors; 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. Most deposits received from outside the United States require an import permit from the U.S. Department of Agriculture (USDA). Also required is a Public Health Services (PHS) permit, available from the Centers for Disease Control and Prevention (CDC), for importation of agents infectious to humans. There is no extra charge for this permit application processing. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to $5,000,000.

In addition, this collection does have postage costs. Biological deposits are generally shipped to the depository "Domestic Overnight" by Federal Express (FedEx) and, since depositors are urged to supply frozen or freeze-dried material, it must be packed in dry ice according to a representative from the Patent Department at ATCC. Dry ice itself is considered dangerous goods and requires special packaging. Additional FedEx special handling charges for inaccessible dangerous goods shipments of $37.50 per shipment apply for temperature-sensitive biological materials and also for the dry ice. An average cost for shipping by FedEx "Domestic Overnight" is estimated to be $75. If the shipment requires a pick-up by FedEx, there is an additional charge of $4. Special packaging is also required for these shipments. According to DG Supplies Inc., a supplier of infectious and diagnostic goods packaging, the average cost of frozen infectious shippers is estimated to be $352.82 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, postage costs average $469.32 per shipment, for a cost to respondents of $938,640.

The postage cost for a depository seeking recognition is estimated to be $5.95, sent to the USPTO by priority mail through the United States Postal Service. Since the USPTO estimates that it receives one request for recognition from a depository every four years, the postage cost averages $5.95 per depository request, for a rounded cost to respondents of $6.00.

Table 3 – Annual (Non-hour) Costs to Respondents

Item #	Item/Type of Cost	Estimated Annual Responses	Amount	Totals
	FEES			
1	Deposited Materials	2,000	$2,500.00	$5,000,000.00
2	Request for Depository Approval	1	$0.00	$0.00
	Total Fees			**$5,000,000.00**
	PACKAGING/POSTAGE COSTS			
1	Deposited Materials – Federal Express	2,000	$116.50	$233,000.00
1	Deposited Materials – Packaging Supplies	2,000	$352.82	$705,640.00
2	Request for Depository Approval	1	$5.95	$6.00
	Total Postage/Packaging			**$938,646.00**
	Total Annual (Non-Hour) Cost Burden			**$5,938,646.00**

14. Annual Cost to the Federal Government

For clarity, the burden explanations for the annual cost to the Federal Government have been separated into sections a. and b. Table 4 combines both the deposits of biological material and depositories' information and calculates the burden hours and costs of this information collection to the Federal Government, based on the following factors:

a. Deposited Materials

The USPTO estimates that it takes a GS-11, step 1 examiner, approximately 15 minutes (0.25 hours) to verify that biological materials have been deposited in compliance with the patent statute and regulations. The hourly rate for a GS-11, step 1 examiner (on the complex biotechnology scale) is currently $33.60 according to the U.S. Office of Personnel Management's (OPM's) wage chart, including locality pay for the Washington, DC area. When 30% is added to account for a fully-loaded hourly rate (benefits plus overhead), the rate per hour for a GS-11, step 1, is $43.68 ($33.60 + $10.08).

b. Request for Depository Approval

The USPTO estimates that it would take a GS-15, step 5, approximately 10 hours to recognize an applicant as a suitable depository. The hourly rate for a GS-15, step 1, is currently $67.21 according to OPM's wage chart, including locality pay for the Washington, DC area. When 30% is added to account for a fully-loaded hourly rate (benefits plus overhead), the rate per hour for a GS-15, step 5, is $87.37 ($67.21 + $20.16).

Table 3 calculates the processing hours and costs associated with this information collection to the Federal Government:

Table 4: Burden Hour/Burden Cost to the Federal Government

Item #	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/hr) (e) (c) x (d)
1	Deposited Materials	0.25	2,000	500	$43.68	$21,840.00
2	Request for Depository Approval	10.0	1	10	$87.37	$874.00
	Total	**- - - - -**	**2,001**	**510**	**- - - - -**	**$22,714.00**

15. Reason for Change in Burden from the Current Inventory

OMB previously approved this information collection in August 2010 with a total of 3,501 responses, 3,505 burden hours, and $9,831,120 in annual (non-hour) costs. There have been no interim approvals.

Changes in Responses and Burden Hours from the Current Inventory

The USPTO estimates that the total annual responses will be 2,001 and the total annual burden hours will be 2,005, which is a decrease of 1,500 responses and 1,500 burden hours from the currently approved burden for this collection. These changes are due to administrative adjustments from updated annual response estimates.

Table 4a: Changes in Responses and Burden Hours from the Current Inventory

Item #	Item	Currently Approved responses	Updated responses	Change in responses (admin.)	Currently approved burden hours	Updated burden hours	Change in burden hours (admin.)
1	Deposited Materials	3,500	2,000	(1,500)	3,500	2,000	(1,500)
2	Request for Depository Approval	1	1	0	5	5	0
	Totals	**3,501**	**2,001**	**(1,500)**	**3,505**	**2,005**	**(1,500)**

Changes in Annual (Non-hour) Costs from the Current Inventory

The total annual (non-hour) cost burden for this submission of $5,938,646 is a decrease of $3,892,474 from the currently approved total of $9,831,120. This decrease is due to administrative adjustments from a decrease in response estimates and updated mailing/postage rates.

Table 4b: Changes in Annual (Non-hour) Costs from the Current Inventory

Item #	Cost	Currently approved annual cost burden	Program changes	Administrative adjustments	Total change in costs	Updated annual cost burden
1 & 2	Mailing/Postage	$9,831,120.00	$0.00	$3,892,474.00	$3,892,474.00	$5,938,646.00
	Totals	**$9,831,120.00**	**$0.00**	**$3,892,474.00**	**$3,892,474.00**	**$5,938,646.00**

16. Project Schedule

The USPTO does not plan to publish this information for statistical use. However, notice of recognized, defaulted or discontinued depositories is required to be published in the *Official Gazette of the United States Patent and Trademark Office.*

17. Display of Expiration Date of OMB Approval

There are no forms associated with this collection. Therefore, the display of the expiration date is not applicable.

18. Exception to the Certificate Statement

This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.