SUPPORTING STATEMENT
United States Patent and Trademark Office
Deposit of Biological Materials
OMB CONTROL NUMBER 0651-0022
January 2020

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the information collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

This information collection covers information from patent applicants who seek to deposit biological materials as part of a patent application in accordance with the America Invents Act. 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 information collection also covers applications from institutions that wish to be recognized by the United States Patent and Trademark Office (USPTO) as a suitable depository to receive deposits for patent 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, sometimes words and figures are not sufficient to satisfy the statutory requirement for patentability under 35 U.S.C. 112 (every patent must contain a description of the invention sufficient to enable a person (knowledgeable in the relevant science), to make and use the invention as specified by 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, 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 also must 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. 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 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 is not able to self-replicate, and a replacement or supplemental deposit needs to be made. In that event, this information collection covers the requirement that the depositor 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.

There are no forms associated with the information collected by the USPTO in connection with the deposit of biological materials.

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 to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications. This information collection covers the information gathered in the request to allow the USPTO to evaluate whether such an institution has demonstrated that its 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. For example, this activity covers documentation from depositories that verifies that their practices and procedures, the technical competence of their staff, and their facilities fulfill the stringent requirements spelled out under the regulations.

This activity also covers additional information gathered by the USPTO that may be needed after a depository has been recognized by the USPTO. For example, this information collection covers 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 are no forms associated with requests to become a recognized depository.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new information collection, indicate the actual use the agency has made of the information received from the current information collection.

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 collected, maintained, and used in this information collection is based on OMB and USPTO guidelines. This includes the basic information quality standards established in the Paperwork Reduction Act (44 U.S.C. Chapter 35), in OMB Circular A-130, and in the USPTO information quality guidelines.

Table 1 provides the specific statutes and regulations 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	Regulation	Form #	Needs and Uses
1	Deposit of Biological Materials	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. • 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 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 regulations and guidance.

Item #	Requirement	Statute	Regulation	Form #	Needs and Uses
2	Depositories	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. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological information collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of information collection. Also describe any consideration of using information technology to reduce burden.

The deposit of biological material information is uploaded into the USPTO's Web-based Electronic Filing System (EFS-Web) to accompany other patent application information. However, the deposit of the physical specimen itself cannot be done electronically. Currently, the USPTO does not use automated, electronic, mechanical, or other

technological collection techniques for depositories seeking consideration as an acceptable depository. As the USPTO expands electronic filing under the EFS-Web, the Deposit of Biological Materials Program will be evaluated to determine whether electronic filing is feasible and practicable. 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. **Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

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

5. **If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.**

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. USPTO estimates that 3% of the respondents in this information collection are small entities.

6. **Describe the consequence to Federal program or policy activities if the information collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

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 was 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. **Explain any special circumstances that would cause an information collection to be conducted in a manner:**

• requiring respondents to report information to the agency more often than quarterly;
• requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
• requiring respondents to submit more than an original and two copies of any document;
• requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
• in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

• requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
• that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
• requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

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

8. **If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of information collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.**

The 60-Day Notice was published in the *Federal Register* on November 26, 2019 (84 FR 63855). The comment period ended on January 21, 2020. 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. **Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees**.

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

10. **Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the**

information collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

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.

Applications filed through EFS-Web are maintained in confidence as required by 35 U.S.C. § 122(a) until the application is published or a patent is issued. The confidentiality, security, integrity, authenticity, and non-repudiation of patent applications submitted electronically through EFS-Web are maintained using PKI technology and digital certificates for registered users. Applications electronically-filed by non-registered users are protected using Transport Layer Security (TLS) or Secure Sockets Layer (SSL) protocols. The USPTO posts issued patents and application publications on its Web site. The information covered under this information collection will not be released to the public unless it is part of an issued patent or application publication. Patent applicants and/or their designated representatives can view the current status of their patent application through the Patent Application Information Retrieval (PAIR) system.

Patent applications and associated materials may contain data which is subject to the Privacy Act. This information is collected on submissions filed to obtain various patent products. The following SORNs provide privacy disclosures and information about USPTO's handling of personally identifiable information (PII) that may be collected in this information collection:

- PAT/TM 7 Patent Application Files; published March 29, 2013 (78 FR 19243)

These provisions only apply to items held by USPTO. Items being held by a deposit arrangement with a 3rd party are not covered by these any of these obligations regarding privacy or confidentiality.

Information sent to USPTO by institutions wishing to be recognized by the USPTO as a suitable depository are not covered by either the statues regarding confidentiality of patent applications or included in the Privacy Act provisions. They are provided no other assurance except for protection under the FOIA regulations.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom

the information is requested, and any steps to be taken to obtain their consent.

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

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.**

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. Deposits of Biological Materials

- **Respondent Calculation Factors**

  The USPTO estimates that approximately 950 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 3% 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 uses a professional rate of $28.14 for a senior administrative assistant (BLS rate; 43–1011[1] First Line Supervisors of Office and Administrative Support Workers) to collect and submit the deposit information. When 30% is added to account for a fully-loaded hourly rate (benefits plus overhead), the rate per hour is $36.58 ($28.14+$8.44).

b. Depositories

- **Respondent Calculation Factors**
  No depository has requested recognition by the USPTO to serve as a depository of biological materials since September 1994, but 5 existing depositories were grandfathered under current law in 1994. For the purpose of this submission, the USPTO estimates that one depository might seek recognition 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.

  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 $68.22 per hour for those completing a Request for Depository Approval, which is the mean rate for attorneys in private firms as shown in the Bureau of Labor Statistics (BLS rate; 23-1011[2] Lawyers). When 30% is added to account for a fully-loaded hourly rate (benefits plus overhead), the rate per hour for an attorney, is $85.98 ($20.47 + $68.22).

[1] https://www.bls.gov/oes/2017/may/oes431011.htm
[2] https://www.bls.gov/oes/2017/may/oes231011.htm

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	1.0	950	950	$36.58	$34,751
2	Request for Depository Approval	5.0	1	5	$85.98	$430
	Total	**- - -**	**951**	**955**	**- - -**	**$35,181**

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

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 $2,375,000; (950 respondents X $2,500).

In addition, this information collection has 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 $40 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 $471.82 per shipment, for a cost to respondents of $448,229; (950 respondents X $471.82).

The postage cost for a depository seeking recognition is estimated to be $7.65, 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 4 years, the postage cost averages $7.65 per depository request. The total estimated postage costs in this information collection is $448,237.

Therefore, the USPTO estimates that the total (non-hour) respondent cost burden for this information collection in the form of capital start-up costs and postage costs is $2,823,237

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

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. Deposits of Biological Material

The USPTO estimates that it takes a GS-11, step 1[3] 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 is currently $34.51. 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 $44.86 ($34.51+ $10.35).

b. Depositories

The USPTO estimates that it would take a GS-15, step 5[4], approximately 10 hours to recognize an applicant as a suitable depository. The hourly rate for a GS-15, step 5, is currently $77.49. 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 $100.74 ($77.49 + $23.25).

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

Table 3: 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	950	238	$44.86	$10,677
2	Request for Depository Approval	10.0	1	10	$100.74	$1,007
	Total	**- - -**	**951**	**248**	**- - -**	**$11,684**

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

A. Changes in information collection since previous OMB approval in 2016

[3] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf
[4] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf

OMB previously approved this information collection in November 2016. This information collection, as currently approved, contains an estimated:

- 901 responses
- 905 burden hours
- $2,674,644 annual (non-hourly) cost burden

B. Changes proposed in this request to OMB

The proposed information collection, as outlined in the tables above, seeks to modify the existing information collection. The proposed information collection, if approved, is estimated to contain:

- 951 responses
- 955 burden hours
- $2,823,237 annual (non-hour) cost burden

These changes are due to the following adjustments:

The USPTO estimates that this information collection will receive 50 more annual responses (for the deposits of biological materials activity, in particular) over the 3-year period covered by this renewal request. This adjustment caused the number of burden hour to increase by 50 hours. In addition, this adjustment, along with increased estimated hourly rates, caused the annual cost burden to increase by $148,593.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

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. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

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

18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

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.