SF-83 SUPPORTING STATEMENT
PAPERWORK REDUCTION ACT – OMB CONTROL NUMBER 0651-0022
DEPOSIT OF BIOLOGICAL MATERIALS

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 the United States Patent and Trademark Office (USPTO) approval 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, Deposits of Biological Materials

The deposit of biological materials as part of a patent application is required by 35 U.S.C. § 2(b)(2) and 37 CFR 1.801-1.809. Every patent must contain a written 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. The term biological includes material that is capable of self-replication, either directly or indirectly. When the invention involves a biological material, sometimes words alone cannot sufficiently describe how to make and use the invention in a reproducible or repeatable manner. In such cases, the required biological material must either be known and readily (and continually) available, or be deposited in a suitable depository to meet the enablement and written description requirements of 35 U.S.C. § 112.

In cases where a novel microorganism is involved, the USPTO traditionally requires the deposit of a sample with a recognized patent depository in order to meet the above disclosure requirements. When a deposit is necessary, the USPTO collects information to determine whether the depositor is in compliance with the patent statute. This includes a statement proving notification to the interested public on where to obtain samples of the deposits. A viability statement showing that the biological material was tested by the depository, and is a viable or acceptable deposit, must also be submitted to the USPTO.

Once a depositor has deposited biological materials into a recognized depository, occasions may arise causing 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 materials with any International Depository Authority (IDA).

b. Depositories

Depositories are required by 37 CFR 1.803 to demonstrate 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 facilities are sufficient to protect the integrity of the biological materials being stored.

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, 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, which verifies that their practices and procedures, the technical competence of their staff, and their facilities fulfill the stringent requirements spelled out under this rule.

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*.

Table 1 provides the specific statutes and rules requiring the USPTO to collect the information discussed above:

Table 1: Information Requirements for the Deposit of Biological Materials

Requirement	Statute	Rule
Deposit of Biological Materials	35 U.S.C. § 2(b)(2) 35 U.S.C. § 112	37 CFR, 1.801-1.809
Depositories	35 U.S.C. § 2(b)(2)	37 CFR 1.803

2. Needs and Uses

This information is used by the USPTO to determine whether or not 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 comply with all applicable information quality guidelines, *i.e.,* OMB and specific operating unit guidelines.

This proposed collection of information would result in information that will be collected, maintained, and used in a way consistent with all applicable OMB and USPTO Information Quality Guidelines (See Attachment A).

Tables 2 and 3 outline how this information is collected and used by the USPTO and by the public. No forms are associated with this collection.

Table 2: Needs and Uses of Information Collected for the Deposit of Biological Materials

Requirement	Form #	Needs and Uses
Deposit of Biological Materials	No Form Associated	• Used by the applicant to determine whether to file for a new patent. • Used by the patentee to maintain enforceability of a patent. • Used by the USPTO to establish enablement of claimed biological materials. • Used by the USPTO to establish possession of the invention for priority purposes.

Table 3: Needs and Uses of Information Collected for Depository Approval

Requirement	Form #	Needs and Uses
Depositories	No Form Associated	• Used by the respondent depositories to determine the requirements that they must follow in order to be recognized by the USPTO. • 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 the Office of Management and Budget (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. Consultation Outside the Agency

The 60-Day Notice was published in the *Federal Register* on October 25, 2006 (71 Fed Reg. 62423). The comment period ended on December 26, 2006. 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, inventor groups, and users of our public facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. There have been no comments or concerns expressed by these or similar organizations concerning the time required to provide the information required under this program.

9. Payment or Gifts to Respondents

This information collection does not involve a payment or gift to any respondent. Response to this information collection is necessary to obtain a patent or to obtain status as a suitable depository.

10. Assurance of Confidentiality

Confidentiality of patent applications is governed by 35 U.S.C. § 122 and 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. The disclosure of the invention in the application is the quid pro quo for the property right conferred by the patent grant and the very means by which the patent statute achieves its constitutional objective of "promot[ing] the progress of sciences and useful arts." The prosecution history contained in the application file is critical to determining the scope of the property right conferred by the patent grant.

11. Justification for Sensitive Questions

None of the required information is considered to be of a sensitive nature.

12. Estimate of Hour and Cost Burden to Respondents

For clarity, the burden explanations have been separated into sections a. and b. Table 4 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 3,500 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.

- **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 one (1) hour annually.

- **Cost Burden Calculation Factors**
  The USPTO believes that a senior administrative assistant, at a rate of $30 per hour, would prepare this information. This is a fully loaded hourly rate.

b. Depositories

- **Respondent Calculation Factors**
  No depository has requested recognition by the USPTO to serve as a depository of biological materials since September 1994. The 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, equivalent to 0.25 responses annually.

- **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 five (5) hours spent in collecting and submitting the necessary approval information.

- **Cost Burden Calculation Factors**
  The professional rate of $304 per hour used in this submission to calculate the respondent cost burden is the median rate for associate attorneys in private firms as published in the 2005 report of the Committee on Economics of Legal Practice of the American Intellectual Property Law Association. This report summarized the results of a survey with data on hourly billing rates. This is a fully loaded hourly rate.

Table 4: Burden Hour/Burden Cost to Respondents for the Deposit of Biological Materials

Item	Hours Per Application (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/hr) (e) (c) x (d)
Deposited Materials	1.0	3,500	3,500	$30.00	$105,000.00
Depository Approval	5.0	0.25	1.25	$304.00	$380.00
Total	**- - - - -**	**3,500**	**3,501**	**- - - -**	**$105,380.00**

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 ATCC Bioscience Laboratory Services listing, which includes their requirements along with a fees and payment schedule, is furnished (Attachment B).

The USPTO estimates that approximately 3,500 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. Therefore, depository fees are estimated to be $8,750,000 ($2,500 x 3,500).

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 $32.50 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 $2.20. 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 $199.19 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, postage costs average $308.89 per shipment, for a cost to respondents of $1,081,115 ($308.89 x 3,500).

The postage cost for a depository seeking recognition is estimated to be $4.05, 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 costs average $4.05 per depository request, for a cost to respondents of $1.00 ($4.05 x 0.25).

The USPTO estimates that the (non-hour) respondent cost burden in the form of postage costs amounts to $1,081,116 ($1,081,115 + $1).

Therefore, the USPTO estimates that the total (non-hour) respondent cost burden for this collection in the form of depository fees ($8,750,000) and postage costs ($1,081,116) amounts to $9,831,116.

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 5 combines both the deposits of biological material and 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 Material

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 $31.60 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 $41.08 ($31.60 + $9.48).

b. Depositories

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 $59.93 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 $77.91 ($59.93 + $17.98).

Table 5 calculates the processing hours and costs associated with this information collection to the Federal Government:

Table 5: Burden Hour/Burden Cost to the Federal Government for the Deposit of Biological Materials

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/hr) (e) (c) x (d)
Deposited Materials	0.25	3,500	875	$41.08	$35,945.00
Depository Approval	10.0	0.25	3	$77.91	$234.00
Total	- - - - -	**3,500**	**878**	- - - - -	**$36,179.00**

15. Reason for Change in Burden

Summary of Changes Since the Previous Renewal

This information collection was previously approved by OMB on April 1, 2004, with a total of 3,500 responses and 3,501 burden hours. With this renewal, the USPTO estimates that the annual responses and burden hours will remain the same.

OMB approved the renewal of this collection with $5,562,551 in total annual (non-hour) cost burden. After the collection had been submitted to OMB for review, it came to the attention of the USPTO that the American Type Culture Collection (ATCC) began offering comprehensive patent services for one price in the way of expanded services and fee changes, effective January 1, 2004. Therefore, the annualized capital/start-up costs were recalculated to account for this change, and a change worksheet was submitted to OMB after the approval to adjust the annualized (non-hour) cost burden to $9,727,551.

The total annualized (non-hour) cost burden for this renewal of $9,831,116 is an increase of $103,565 from the currently approved total of $9,727,551. The increase in costs for the current renewal is due to an increase in shipping/packaging costs, as an administrative adjustment.

Changes in Burden Estimates Since the 60-Day Notice

On October 25, 2006, the USPTO published a 60-Day Notice in the *Federal Register* containing the burden estimates for this collection of 3,501 responses, 3,505 in burden hours, and $106,520 in respondent cost burden.

There has been a change to the estimated responses and burden hours since the publication of the 60-Day Notice. The 60-Day Notice reported the responses for depository approval at 1 response and respondent burden hours at 5 hours. It was decided to revert back to the original estimate of one depository seeking recognition every 4 years, equivalent to 0.25 annually. This decreases the respondent cost burden by $1,140, from $106,520 as reported in the 60-Day *Federal Register* Notice to $105,380.

The 60-Day Notice also reported total (non-hour) cost burden in the amount of $9,850,929. Annual costs in the way of non-hour cost burden are being decreased in this submission to $9,831,116 due to a re-evaluation in the shipping/packaging costs.

Change in Respondent Cost Burden

When this collection was approved by OMB in April 2004, the estimated hourly rate for attorneys was $286. Using that rate and the paraprofessional rate of $30, the reported 3,501 burden hours yielded a respondent cost burden of $105,358.

For this renewal, the USPTO is using the current professional hourly rate of $304. At this rate and the administrative rate of $30, the 3,501 burden hours yield a respondent cost burden of $105,380, which is an increase of $22 over the currently approved burden at the previous hourly rate. This increase in respondent cost burden is due to the increase in the estimated hourly professional rate.

Changes in Annualized (Non-hour) Cost Burden

The USPTO estimates that the total annual (non-hour) cost burden will increase by $103,565 for this renewal, from $9,727,551 currently reported on the OMB inventory to the present $9,831,116 per year. The increase is due to an increase in packaging/shipping costs. **Therefore, this collection has an increase in annual (non-hour) cost burden of $103,565 due to an administrative adjustment.**

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.

LIST OF ATTACHMENTS

A. USPTO Information Quality Guidelines
B. American Type Culture Collection (ATCC) Bioscience Laboratory Services listing, requirements, and fees and payment schedule for patent deposits.