

general public and other Federal agencies to take this opportunity to comment on the continuing and proposed information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before November 4, 2003.

ADDRESSES: Direct all written comments to Susan K. Brown, Records Officer, Office of the Chief Information Officer, Office of Data Architecture and Services, Data Administration Division, 703-308-7400, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313, Attn: CPK 3 Suite 310; by e-mail at susan.brown@uspto.gov; or by facsimile at 703-308-7407.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Robert J. Spar, Director, Office of Patent Legal Administration, United States Patent and Trademark Office (USPTO), P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 703-308-5107; or by e-mail at bob.spar@uspto.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The deposit of biological materials as part of a patent application is required by 35 U.S.C. 2(b)(2) and outlined in 37 CFR chapter 1, subpart G, 1.801-809. 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. 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.

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 Depository Authority (IDA).

II. Method of Collection

By mail, facsimile, or hand delivery to the USPTO when the applicant or agent

depending upon the type of deposit being tested. 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 Service (PHS) permit, available from the Centers for Disease Control and Prevention (CDC), for importation of agents infectious to humans. This permit application processing fee is \$150. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to \$1,460.

In addition, this collection does have postage costs. Biological deposits are

files a patent application with the USPTO or submits subsequent papers during the prosecution of the application to the USPTO.

III. Data

OMB Number: 0651-0022.

Form Number(s): None.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; and the Federal Government.

Estimated Number of Respondents: 3,500 responses per year for deposited materials and 0.25 per year for depository approval.

Estimated Time Per Response: The USPTO estimates that it will take approximately 1 hour per application for deposited materials and 5 hours per application for depository approval.

Estimated Total Annual Respondent Burden Hours: 3,501 hours per year.

Estimated Total Annual Respondent Cost Burden: \$105,315 per year to submit the information to the USPTO. Using the professional hourly rate of \$30 for a senior administrative assistant, the USPTO estimates \$105,000 per year for salary costs associated with collecting and submitting the necessary deposit information. Using the professional hourly rate of \$252 for associate attorneys in private firms, the USPTO estimates \$315 per year for salary costs associated with the average depository seeking approval to store biological material.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Deposited Materials	1 hour	3,500	3,500
Depository Approval	5 hours	0.25	1.25
Total	3,500	3,501

Estimated Total Annual Non-hour Respondent Cost Burden: \$979,010. There are no maintenance 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, charges a one-time fee of \$1,150 per deposit for basic storage and informing, and a minimum of \$160 per deposit for viability testing,

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 of \$60 per shipment apply for temperature-sensitive biological material and also for the dry ice. An average cost for shipping by FedEx Domestic Overnight is estimated to be \$75. If the shipment requires pick-up by FedEx, there is an