

The USPTO uses the sequence listings during the examination process to determine the patentability of the associated patent application. Sequence listings are also disclosed as part of the published patent application or issued patent. Sequence listings that are extremely long (more than 600K or approximately 300 typed pages) are published only in electronic form and are available to the public on the USPTO sequence data web page.

Patent applications that contain nucleotide and/or amino acid sequence disclosures must include a copy of the sequence listing in accordance with the requirements in 37 CFR 1.821–1.825. Previously, the rules of practice required applicants to submit a paper copy of the sequence listing as the official archival copy. Due to the recognition that the submission of massive paper versions of extremely long sequence listings was a significant burden on applicants and the USPTO and of minimal utility for examination purposes, the USPTO amended the rules of practice in a Final Rule Notice published in the **Federal Register** on September 8, 2000, entitled “Changes to Implement the Patent Business Goals” (Vol. 65, No. 175), to allow the official copy of the sequence listing under 37 CFR 1.821(c) to be submitted either in paper or on compact disc (CD).

Under 37 CFR 1.821(e), applicants must also submit a copy of the sequence listing in “computer readable form” (CRF) with a statement indicating that the CRF copy of the sequence listing is identical to the official paper or CD copy required by 1.821(c). If an applicant later submits an amendment to the paper or CD copy of the sequence

listing, a new CRF copy of the amended listing must also be submitted.

Applicants may submit the CRF copy of the sequence listing to the USPTO on CD, as provided in 37 CFR 1.824. Sequence listings may also be filed electronically using the Electronic Filing System (EFS) software developed by the USPTO for secure transmission of patent applications and related documents over the Internet. Applicants may use EFS to file a sequence listing electronically with a patent application or subsequent to a previously filed application.

There are no paper forms associated with the collection of sequence information filed with a patent application. Applicants who submit sequence listings electronically using EFS must complete the electronic transmittal forms provided within the electronic submission software provided by the USPTO. If a sequence listing is filed via EFS subsequent to a previously filed application, the CRF copy may be submitted electronically but the applicant must also mail a paper or CD copy of the sequence listing to the USPTO along with a statement indicating that the paper or CD copy and the CRF copy are identical.

In November 2001, OMB approved a change worksheet that increased the burden for this information collection due to increases in patent application filings involving nucleotide and amino acid sequence listings. However, although the total number of annual responses for this collection increased, the proportion of these responses that were submitted electronically was lower than originally estimated.

II. Method of Collection

By mail, hand delivery, or electronically over the Internet to the USPTO.

III. Data

OMB Number: 0651–0024.

Form Number(s): None.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; not-for-profit institutions; farms; the Federal Government; and state, local or tribal governments.

Estimated Number of Respondents: 23,750 responses per year.

Estimated Time Per Response: The USPTO estimates that it will take the public approximately 1 hour and 20 minutes (1.33 hours) to gather the necessary information, prepare the paper sequence listing, and submit it to the USPTO. For sequence listings prepared on CD, the USPTO estimates that it will take the public approximately 1 hour to prepare and submit the sequence listing. For submissions filed electronically using EFS, the USPTO estimates that it will take the public approximately 10 minutes (0.17 hours) to prepare and submit the sequence listing.

Estimated Total Annual Respondent Burden Hours: 29,856 hours per year.

Estimated Total Annual Respondent Cost Burden: \$895,680 per year. The USPTO expects that the information in this collection will be prepared by paraprofessionals at an estimated rate of \$30 per hour. Therefore, the USPTO estimates that the respondent cost burden for this collection will be \$895,680 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Sequence Listing in Application (paper)	1.33 hours	18,880	25,110
Sequence Listing in Application (CD)	1 hour	4,720	4,720
Electronic Sequence Listing in Application (EFS)	10 minutes	150	26
Total	23,750	29,856

Estimated Total Annual Non-hour Respondent Cost Burden: \$50,598 per year. There are no maintenance costs or filing fees associated with this collection. There is no separate filing fee for submitting a sequence listing as part of a patent application. The USPTO also provides PatentIn authoring software for creating the sequence listing in the proper format, which may be downloaded at no cost from the USPTO Web site. However, this collection does

have annualized costs in the form of capital start-up costs, recordkeeping costs, and postage costs.

There are capital start-up costs associated with submitting sequence listings to the USPTO on CD. Producing a CD requires additional hardware, software, and supplies, including a CD drive capable of recording onto CD media (a “CD burner”), CD recording software, blank recordable CD (CD-R) media, cases and labels for the CDs, and a padded mailing envelope for shipping.

The cost of a CD burner is approximately \$200, depending on the speed and type of PC connection. Commercial software for recording CDs retails for approximately \$100, although basic CD recording software is typically included with the CD burner. The cost of blank CD-R media with plastic cases is approximately \$10 for 10 blank CDs, and the cost of software and supplies for labeling CDs is approximately \$20. Padded mailing envelopes for safely