



## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

### Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

**ACTION:** Notice and request for comment

**SUMMARY:** The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, 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 *{insert date 60 days after the date of publication in the Federal Register, in the format “month, day, year”}*.

**ADDRESSES:** Written comments may be submitted by any of the following methods:

- *Email:* InformationCollection@uspto.gov. Include “0651-0024 inquiry” in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-7728; or by e-mail at Raul.Tamayo@uspto.gov with “0651-0024 inquiry” in the subject line. Additional information about this collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

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. Applicants may submit sequence listings for both U.S. and international patent applications. Submissions of sequence listings in international applications are in accordance with Patent Cooperation Treaty (PCT) Rule 13<sup>ter</sup>.

This information collection contains the sequence listing information itself. Information pertaining to the filing of the initial U.S. application is collected under OMB Control Number 0651-0032, and information pertaining to the filing of the initial international application is collected under OMB Control Number 0651-0021.

In particular, this information collection accounts for sequence listings submitted on paper, compact disc (CD), or through EFS-Web, the USPTO’s online filing system. For U.S. applications, 37 CFR 1.821(c) permits all three modes of submission: paper,

CD, or EFS-Web. Sequence listings for international applications may be submitted on paper or through EFS-Web only, though sequence listings that are too large to be filed electronically though EFS-Web may be submitted on a separate CD.

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.

This information collection also contains requests for transfer of a computer readable form under 37 CFR 1.821(e). Under 37 CFR 1.821(e)-(f), applicants who submit their sequence listings on paper or CD must 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 paper or CD copy required by 1.821(c). Applicants may submit the CRF copy of the sequence listing to the USPTO on CD or other acceptable media as provided in 37 CFR 1.824. Sequence listings that are submitted online through EFS-Web in the proper text format do not require a separate CRF copy or the associated statement.

If the CRF sequence listing in a new application is identical to the CRF sequence listing of another application that the applicant already has on file at the USPTO, 37 CFR 1.821(e) permits the applicant to refer to the CRF listing in the other application, rather than having to submit a duplicate copy of the CRF listing for the new application. In such a case, the applicant may submit a letter identifying the application and CRF sequence listing that is already on file and stating that the sequence listing submitted in the new application is identical to the CRF copy already filed with the previous

application. The USPTO provides a form, Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93), in order to assist customers in submitting this statement.

## **II. Method of Collection**

By mail, hand delivery, or electronic submission to the USPTO.

## **III. Data**

*OMB Number:* 0651–0024.

*Type of Review:* Revision of a currently-approved collection.

*Affected Public:* Individuals or households; business or other for-profit organizations; and not-for-profit organizations.

*Estimated Number of Respondents:* 27,200 responses per year. Of this total, the USPTO expects that 25% will be from small entities.

*Estimated Time per Response:* The USPTO estimates that it will take approximately 6 minutes (0.10 hours) to 6 hours to complete a single IC item in this collection, depending on the instrument. This includes the time to gather the necessary information, create the documents, and submit the completed request to the USPTO.

*Estimated Total Annual Hour Burden:* 152,285 hours.

*Estimated Total Annual Cost Burden (Hourly):* \$26,260,375.00. The USPTO estimates that a sequence listing will take approximately five hours of paraprofessional time at an estimated rate of \$125 per hour and one hour of attorney time at \$410 per hour, for a weighted average rate of \$172.50 per hour for preparing a sequence listing. The

USPTO expects that the Request for Transfer of a CRF will be prepared by a paraprofessional at an estimated rate of \$125 per hour. Using this hourly rate, the USPTO estimates \$26,260,375.00 per year for the total hourly costs associated with respondents.

**Table 1: Burden Hour/Burden Cost to Respondents**

IC Number	Item	Estimated Response Time (Hours) (a)	Estimated Annual Responses (b)	Estimated Annual Burden Hours (a) x (b) = (c)	Rate (\$/hr) (d)	Total Cost (\$/yr) (c) x (d) = (e)
1	Sequence Listing in Application (paper)	6.00	6,000	36,000	\$172.50	\$6,210,000.00
1	Sequence Listing in Application (CD)	6.00	350	2,100	\$172.50	\$362,250.00
1	Sequence Listing in Application (electronic)	6.00	19,000	114,000	\$172.50	\$19,665,000.00
2	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	0.10	1,850	185	\$125.00	\$23,125.00
	<b>Totals</b>	.....	<b>27,200</b>	<b>152,285</b>	.....	<b>\$26,260,375.00</b>

*Estimated Total Annual Cost Burden (Non-Hourly):* \$1,774,500.00. This collection has no capital startup, maintenance, or operating fees. This collection does have a non-hourly cost burden in the form of filing fees and postage costs.

Filing Fees

In accordance with 35 U.S.C. § 41(a)(1)(G), the USPTO only charges a fee for submitting a sequence listing as part of a U.S. application or as part of an international application entering the U.S. national stage if the sequence listing (i) is not filed via EFS-Web or not filed on an electronic medium in compliance with §§ 1.52(e) and 1.821(c) or (e), and (ii) causes the application to exceed 100 pages. (See 37 CFR 1.52(f).) Under 37 CFR 1.16(s) and 1.492(j) for U.S. applications and international applications entering the U.S. national stage, respectively, if the application, including the sequence listings filed on paper or on a non-compliant electronic medium, exceeds

100 pages, the application size fee is \$400 (or \$200 for small entities and \$100 for micro entities) for each additional 50 pages or fraction thereof. The USPTO estimates the following with respect to the number of applications that will include long sequence listings filed on paper or on a non-compliant electronic medium and the average application size fee that such applications will incur: (i) approximately 200 applications from large entities will incur an average application size fee of \$1,200; (ii) approximately 100 applications from small entities will incur an average application size fee of \$600; and (iii) approximately 40 applications from micro entities will incur an average application size fee of \$300. The estimate corresponds to a total fee cost of \$240,000, \$60,000, and \$12,000, respectively.

As a Receiving Office, the USPTO collects the international filing fee for each international application it receives. The basic international filing fee only covers the first 30 pages of the international application. As a result, a \$15 fee per page is added to the international filing fee for each page over 30 pages of an international application including a sequence listing filed on paper or in PDF format. No page fees are triggered by sequence listings that are submitted via EFS-Web in the proper text format. The average length of a sequence listing filed on paper or in PDF format in an international application is 150 pages, which would carry an additional fee of \$2,250 if the international application were already at least 30 pages long without the listing. The USPTO estimates that approximately 650 of the 6,000 sequence listings filed per year on paper or in PDF format will be for international applications, for a cost of \$1,462,500.

Therefore, the USPTO estimates that the total fee costs for this collection will total \$1,774,500.00.

### Postage Costs

Mailed submissions may include the sequence listing on either paper or CD, the CRF copy of the listing on CD, and a transmittal letter containing the required identifying information. The USPTO estimates that the average postage cost for a paper or CD sequence listing submission will be \$6.45 (USPS Priority Mail, flat rate envelope) and that 6,350 sequence listings will be mailed to the USPTO per year, for a total of \$40,957.50 in postage costs.

With filing fee costs totaling \$1,774,500.00 and postage costs totaling \$40,957.50, the USPTO estimates that the total annual non-hourly cost burden for this collection will amount to \$1,815,457.50.

### **IV. Request for Comments**

Comments are invited on:

- (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
- (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) ways to enhance the quality, utility, and clarity of the information to be collected; and
- (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: March 11, 2016

Marcie Lovett

Records Management Division Director, OCIO,

United States Patent and Trademark Office

**BILLING CODE 3510-16-P**

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