3510-16-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

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

ACTION: Proposed collection; comment request.

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 take this opportunity to comment on the continuing 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 [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: InformationCollection@uspto.gov. Include "0651-0024 comment" in the subject line of the message.
- Mail: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.
- Federal Rulemaking Portal: http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, 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 to Raul.Tamayo@uspto.gov. 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. The rules of practice require applicants

to submit these sequence listings in a standard international format that is consistent with World Intellectual Property Organization (WIPO) Standard ST.25 (1998). Applicants may submit sequence listings for both U.S. and international patent applications.

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 (files larger than 600K or approximately 300 printed pages) are published only in electronic form and are available to the public on the USPTO sequence data Web page (http://seqdata.uspto.gov) as an ASCII text file.

The sequence listing required by 37 CFR 1.821(c) for U.S. patent applications may be submitted on paper, compact disc (CD), or through EFS-Web, the USPTO's online filing system. 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 through EFS-Web may be submitted on a separate CD. Applicants may use EFS-Web to file a sequence listing online with a patent application or subsequent to a previously filed application.

Under 37 CFR 1.821(e)-(f), 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 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.

This information collection contains the sequence listings that are submitted with biotechnology patent applications. Information pertaining to the filing of the initial patent application itself is collected under OMB Control Number 0651-0032, and international applications submitted under the Patent Cooperation Treaty (PCT) are covered under OMB Control Number 0651-0021.

II. Method of Collection

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

III. Data

OMB Number: 0651-0024.

Form Number(s): PTO/SB/93.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 25,250 responses per year. The USPTO estimates that approximately 27% of these responses will be from small entities.

Estimated Time Per Response: The USPTO estimates that it will take the public approximately six minutes (0.10 hours) to six hours (6.0 hours) to gather the necessary

information, prepare the form or sequence listing, and submit it to the USPTO.

Estimated Total Annual Respondent Burden Hours: 138,225 hours.

Estimated Total Annual Respondent Cost Burden: $22,590,450. The USPTO estimates that a sequence listing will take approximately five hours of paraprofessional time at an estimated rate of $122 per hour and one hour of attorney time at $371 per hour, for a weighted average rate of $163.50 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 $122 per hour. Therefore, the USPTO estimates that the respondent cost burden for this collection will be approximately $22,590,450 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Sequence Listing in Application (paper)	6 hours	8,500	51,000
Sequence Listing in Application (CD)	6 hours	500	3,000
Electronic Sequence Listing in Application (EFS-Web)	6 hours	14,000	84,000
Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	6 minutes	2,250	225
Totals		**25,250**	**138,225**

Estimated Total Annual Non-hour Respondent Cost Burden: $2,542,350. This collection has annual (non-hour) costs in

the form of fees and postage costs. The USPTO provides free software for creating and validating the format of sequence listings prior to submission.

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 $320 (or $160 for small entities) for each additional 50 pages or fraction thereof. The USPTO estimates that approximately 250 applications from large entities with long sequence listings filed on paper or on a non-compliant electronic medium will incur an average application size fee of $960, and approximately 200 applications from small entities with long sequence listings filed on paper or on a non-compliant electronic medium will

incur an average application size fee of $480, for a total of $336,000 per year.

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 $16 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 $2,400 if the international application were already at least 30 pages long without the listing. The USPTO estimates that approximately 900 of the 8,500 sequence listings filed per year on paper or in PDF format will be for international applications, for a total of $2,160,000 per year in page fees. Therefore, this collection has a total of $2,496,000 in fees per year.

Customers may incur postage costs when submitting a sequence listing to the USPTO by mail. 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 $5.15 and that 9,000 sequence listings will be mailed to the USPTO per year, for a total postage cost of $46,350 per year.

The total annual (non-hour) respondent cost burden for this collection in the form of fees and postage costs is estimated to be $2,542,350 per year.

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; (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, e.g., the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of

this information collection; they also will become a matter of public record.

Dated: October 24, 2012

Susan K. Fawcett,

Records Officer, USPTO,

Office of the Chief Information Officer.

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