SUPPORTING STATEMENT
United States Patent and Trademark Office
Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures
OMB CONTROL NUMBER 0651-0024
May 2016

A. JUSTIFICATION

1. Necessity of Information Collection

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. Submissions of nucleotide and amino acid sequence listings in international applications are in accordance with Patent Cooperation Treaty (PCT) Rule 13ter.

The USPTO uses the sequence listings during the examination process to determine the patentability of the associated patent application. Sequence listings also are disclosed as part of the published patent application or issued patent.

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 also 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). If an applicant later submits an amendment to the paper or CD copy of the sequence listing, the applicant also must submit a new CRF copy of the amended listing. 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.

Table 1 provides the specific statute and regulations authorizing the USPTO to collect the information discussed above:

Table 1: Information Requirements

IC Number	Requirement	Statute	Rule
1	Sequence Listing in Application	35 U.S.C. § 22	37 CFR 1.821-1.825
2	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e)	35 U.S.C. § 22	37 CFR 1.821-1.825

2. Needs and Uses

The USPTO uses nucleotide and amino acid sequence listing information to determine the patentability of an application during the examination process and to support the publication of issued patents. Upon publication of the application or issued patent, the associated nucleotide or amino acid sequence listings are disclosed to the public and made available on the USPTO Web site. Copies of sequence listings from issued patents may be forwarded to the National Center for Biotechnology Information (NCBI). Applicants use the sequence data when preparing both national and international patent applications involving nucleotide or amino acid sequences.

The information collected, maintained, and used in this collection is based on OMB and USPTO guidelines. This includes the basic information quality standards established in the Paperwork Reduction Act (44 U.S.C. Chapter 35), in OMB Circular A-130, and in the USPTO information quality guidelines.

Table 2 outlines how this collection of information is used by the public and the USPTO:

Table 2: Needs and Uses

IC Number	Item	Form #	Needs and Uses
1	Sequence Listing in Application (paper)	No Form Associated	• Used by the public when preparing a U.S. or international patent application containing nucleotide and/or amino acid sequence information. • Used by the USPTO to determine the patentability of an application. • Used by the USPTO to support publication of applications and issued patents. • Used by the USPTO to provide sequence listings from issued patents to the NCBI.
1	Sequence Listing in Application (CD)	No Form Associated	• Used by the public when preparing a U.S. patent application containing nucleotide and/or amino acid sequence information. • Used by the public when preparing an international patent application containing nucleotide and/or amino acid sequence information that is too large to submit electronically over the Internet. • Used by the USPTO to determine the patentability of an application. • Used by the USPTO to support publication of applications and issued patents.
1	Sequence Listing in Application (electronic)	No Form Associated	• Used by the public to submit a nucleotide and/or amino acid sequence listing electronically with a U.S. national or international patent application or subsequent to a previously filed application. • Used by the USPTO to determine the patentability of an application. • Used by the USPTO to support publication of applications and issued patents. • Used by the USPTO to provide sequence listings from issued patents to the NCBI.
2	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e)	PTO/SB/93	• Used by the public to indicate that a CRF sequence listing in a new application is identical to a CRF sequence listing that is already on file at the USPTO. • Used by the USPTO to transfer a copy of an existing CRF sequence listing to a new application.

3. Use of Information Technology

Applicants may submit sequence listings on paper, CD, or electronically over the Internet. Submissions on CD must follow the guidelines specified in 37 CFR 1.52(e), with the file contents in American Standard Code for Information Interchange (ASCII) format, and be accompanied by the necessary transmittal documentation to identify, maintain, and interpret the sequence listing. Applicants who submit a paper or CD sequence listing also are required to submit a CRF copy of the listing, which facilitates the ability of examiners to search sequences and improves the accuracy and efficiency of the publishing process. Due to PCT guidelines, sequence listings for international applications may not be submitted on CD, except for oversized listings that are too large to submit online as detailed below.

Applicants may submit sequence listings to the USPTO electronically through EFS-Web, the USPTO's online patent application and document submission system that allows customers to file patent applications and associated documents through their standard Web browser. Filers should prepare sequence listings in the proper ASCII text format and then upload them using the secure EFS-Web interface. EFS-Web will display a warning if the sequence listing does not conform to the proper format.

EFS-Web offers many potential benefits to filers. The system immediately sends customers an electronic receipt and ensures that electronic sequence listings are transmitted securely to the USPTO. The electronic filing of sequence listings also eliminates the inefficiencies of physically mailing, handling, routing, and storing sequence listings on paper or portable electronic media. Sequence listings submitted in the proper text format using EFS-Web do not incur any fees and do not require a separate CRF copy or any paper documentation.

Sequence listing files that exceed 100 megabytes may not be submitted online via EFS-Web. These oversized sequence listings should be copied onto CD for submission to the USPTO by mail. Customers are advised to keep a back-up copy of the CD and transmittal information for their own records, and they also may submit a second copy of the CD to the USPTO to be used in case the first copy is unreadable. The acceptance of CDs and electronic submissions is permitted by 35 U.S.C. § 22, which provides that the USPTO "may require papers filed in the Patent and Trademark Office to be printed, typewritten, or on an electronic medium."

The USPTO provides free PatentIn authoring software that may be used by applicants to create sequence listings that comply with U.S. and international filing standards for biotechnology patent applications containing nucleotide and amino acid sequence data. The PatentIn software may be downloaded from the USPTO Web site, and the USPTO offers in-person and online training on how to use the software. In addition, the USPTO provides a CRF Checker software tool that allows applicants to test sequence listings for compliance with format and content rules before submitting them to the USPTO. Use of the Checker utility reduces the number of sequence listings that the USPTO must return to customers for correction of errors.

When the sequence listing arrives at the USPTO, the data format is checked for compliance by the CRF receipt system and then uploaded to the Automated Biotechnology Sequence Search (ABSS) System database. ABSS stores electronic sequence listings submitted by applicants and supports searching of biosequences from patent submissions as well as public and commercial databases of published biosequence data. ABSS also supports the publication and dissemination of sequence listings following publication of the associated application or issuance of the patent.

Upon publication of the application or issued patent, the associated nucleotide or amino acid sequence listings are disclosed to the public. Sequence listings that are extremely long (files larger than 600K or approximately 300 printed pages) are published only in electronic form and are available for public viewing or download through the Publication Site for Issued and Published Sequences (PSIPS) on the USPTO Web site (http://seqdata.uspto.gov). Shorter sequence listings are available through the standard patent and application search systems on the USPTO Web site.

4. Efforts to Identify Duplication

This collection requires the duplication of a limited amount of identifying information (such as the applicant's name, address, and phone number), which is also provided on the patent application. However, the duplication of identification information is the most efficient way of accurately associating the sequence listing with the appropriate application case file.

For sequence listings that are submitted on paper or CD, the applicant also must submit a separate CRF copy of the listing. However, if the applicant already has an identical CRF sequence listing on file at the USPTO for another application, the applicant may submit a statement referencing the CRF listing already on file rather than having to submit a duplicate copy of the CRF listing for the new 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.

5. Minimizing Burden to Small Entities

Although the collection may involve small businesses or other small entities, most applications involving sequence listings are filed by entities other than small entities. This collection does not impose a significant economic impact on small businesses or other small entities. The same information is required from every applicant and is not available from any other source.

The information collection involves payment of fees by customers who may qualify as small entities. To reduce this cost burden for small entities, the USPTO offers reduced application size fees for persons, small business concerns, or nonprofit organizations that qualify as small entities (including micro entities) under 37 CFR 1.27. No significant burden is placed on small entities, in that small entities are simply required to identify themselves as such in order to obtain these benefits. An assertion of small entity status (or a certification of entitlement to micro entity status) only needs to be filed once in an application or patent.

6. Consequences of Less Frequent Collection

This collection of information is required for the processing and examination of the respondent's patent application involving a nucleotide or amino acid sequence listing. This information could not be collected less frequently. If the information were not collected, the USPTO could not properly examine the associated application as required by 35 U.S.C. § 131. Further, the collection of this information is necessary in order to publish the sequence listings accurately as part of the application or patent.

7. Special Circumstances in the Conduct of Information Collection

There are no special circumstances associated with this collection of information.

8. Consultations Outside the Agency

The 60-Day *Federal Register* Notice was published on March 17, 2016 (81 FR 14425). The comment period ended on May 16, 2016. No comments were received from the public.

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, independent inventor groups, and users of our public facilities. The USPTO also is in frequent contact with groups from whom sequence information is collected, such as BIO, the Biotechnology subgroup of the AIPLA, and the Biotechnology Institute. Views expressed by all of these groups are considered in developing proposals for information collection requirements and during the renewal of an information collection. No views have been expressed regarding the present renewal.

9. Payments or Gifts to Respondents

This information collection does not involve a payment or gift to any respondent.

10. Assurance of Confidentiality

The confidentiality of patent applications is governed by statute (35 U.S.C. § 122) and regulation (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.

11. Justification for Sensitive Questions

None of the required information in this collection is considered to be sensitive.

12. Estimate of Hour and Cost Burden to Respondents

Table 3 calculates the burden hours and costs of this information collection to the public, based on the following factors:

- **Respondent Calculation Factors**
  The USPTO estimates that it will receive approximately 271,200 responses per year for this collection, with approximately 25% of these responses submitted by small entities.

These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected by these items.

- **Burden Hour Calculation Factors**
  The USPTO estimates that it will take the public approximately 6 minutes (0.10 hours) to 6 hours to gather the necessary information, prepare the form or sequence listing, and submit it to the USPTO.

  These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected and the length of time necessary to complete responses containing similar or like information.

- **Cost Burden Calculation Factors**
  The USPTO uses a professional rate of $410 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the 2015 *Report of the Economic Survey*, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA).

  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.

Table 3: 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
	Totals	**. . . . . .**	**0**	**02,285**	**. . . . . .**	**$26,260,375.00**

13. Total Annual (Non-hour) Cost Burden

The total annual (non-hour) respondent cost burden for this collection is calculated in Tables 4 and 5 below. This collection has no capital start-up, maintenance, or recordkeeping costs. It does, however, have a non-hour 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.

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.

Table 4: Filing Fee Costs

IC Number	Item	Estimated Annual Responses (a)	Fee Amount (b)	Total Fees (a) x (b) = (c)
1	Size fees under 37 CFR 1.16(s) and 1.492(j), large entity	200	$1,200.00	$240,000.00
1	Size fees under 37 CFR 1.16(s) and 1.492(j), small entity	100	$600.00	$60,000.00
1	Size fees under 37 CFR 1.16(s) and 1.492(j), micro entity	40	$300.00	$12,000.00
1	Size fees for international applications	650	$2,250.00	$1,462,500.00
	Totals	**990**	----------	**$1,774,500.00**

Postage

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.

Table 5: Postage Costs

IC Number	Item	Estimated Annual Responses (a)	Postage Rate (b)	Total Postage Cost (a) x (b) = (c)
1	Postage for paper or CD sequence listing submissions	6,350	$6.45	$40,957.50
----------	**Totals**	**6,350**	**-----**	**$40,957.50**

With 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.

14. Annual Cost to the Federal Government

Sequence disclosures are processed in two stages. The USPTO estimates that the first stage takes approximately 8 minutes of processing time by a GS-6, step 1 employee,

and that the second stage takes approximately 16 minutes of processing time by a GS-12, step 1 or GS-13, step 1 employee, for a total of 24 minutes (0.40 hours) of processing time per response. The hourly rate for a GS-6, step 1 employee is currently $18.84, and the average hourly rate of a GS-12, step 1 ($37.13) and GS-13, step 1 ($44.15) is currently $40.64. These rates produce a weighted average hourly rate of $33.37, which results in a fully-loaded hourly rate of $43.39 per hour ($33.37 with 30% ($10.02) added for benefits and overhead for processing the sequence disclosures.

The USPTO estimates that it takes a GS-6, step 1 employee an average of 8 minutes (0.13 hours) to process a Request for Transfer of a CRF at an estimated fully-loaded cost of $24.49 per hour (GS hourly rate of $18.84 with 30% ($5.65) added for benefits and overhead).

Table 6 calculates the burden hours and costs to the Federal Government for processing this information collection:

Table 6: Burden Hour/Burden Cost to the Federal Government

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)	0.40	6,000	2,400.00	$43.39	$104,136.00
1	Sequence Listing in Application (CD)	0.40	350	140.00	$43.39	$6,074.60
1	Sequence Listing in Application (electronic)	0.40	19,000	7,600.00	$43.39	$329,764.00
2	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	0.13	1,850	246.67	$24.49	$6,040.87
	Totals	. . . . .	**0**	**10,386.67**	. . . . .	**0**

15. Reasons for Changes in Burden from the Current Inventory

OMB previously approved this information collection in February 2013 with a total of 25,250 responses, 138,225 burden hours, and $2,546,400 in annual (non-hour) costs. There have been no interim approvals.

Changes in Responses and Burden Hours from the Current Inventory

For this renewal, the USPTO estimates that the total annual responses will be 27,200 and the total annual burden hours will be 152,285, which are increases of 1,950 responses and 14,060 burden hours from the currently-approved burden for this collection. These increases are due to:

Administrative adjustments

- In developing its burden estimates for this proposed collection, the USPTO updated its projections of the number of respondents that would submit the Sequence Listing in Application and/or the Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) items. The USPTO expects that the number of respondents submitting a Sequence Listing in Application on paper will decrease from 8,500 to 6,000, that the number submitting a Sequence Listing in Application on CD will decrease from 500 to 350, that the number submitting a Sequence Listing in Application electronically will increase from 14,000 to 19,000, and that the number submitting a Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) will decrease from 2,250 to 1,850. These burden adjustments, coupled with the increase in the hourly wage rates used to calculate total hourly cost burden, led to the $3,669,925.00 increase in hourly respondent cost burden for this collection over the previously-approved renewal.

Changes in Annual (Non-hour) Costs from the Current Inventory

The total annual (non-hour) cost burden for this submission of $1,815,457.50 is a decrease of $730,942.50 from the currently-approved total of $2,546,400.00. This decrease is due to:

Program changes

- Filing Fees: The creation and inclusion of a new category of small entity—"micro entity"—led to the addition of a new reduced-fee rate to accommodate that new small-entity category. The rates for this proposed collection are $1,200 (large entity), $600 (small entity), and $300 (micro entity); the corresponding rates from the previous renewal of this collection were $960, $480, and N/A, respectively. This addition adjusted the ratio of large-entity to small-entity items that combined with adjustments in respondent estimates to decrease the total amount of fees collected as size fees under 37 CFR 1.16(s) and 1.492(j).

Administrative adjustments

- Filing Fees: The number of responses to which size fees were applicable fell in all three categories: large-entity responses fell from 250 to 200, small-entity responses fell from 200 to 140 (inclusive of both the 100 small-entity responses and the 40 micro-entity responses in this proposed collection), and international applications fell from 900 to 650.

- Postage: The postage cost for mailing in a single item in this collection rose by $0.85, from $5.60 to $6.45, due to increases in established USPS rates.

Changes in Federal Government Cost Burden from the Current Inventory

The total federal government cost burden for this submission of $446,015.47 is an increase of $53,327.47 from the currently-approved total of $392,688.00. This increase is due to:

Administrative adjustments

- In addition to the adjustment in the number of respondents expected for this collection as outlined above in the "Changes in Responses and Burden Hours from the Current Inventory" item, the GS Wage Tables for the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA locality pay area were updated. As a result, the total federal government cost burden for this proposed collection increased by the amount shown above.

16. Project Schedule

The USPTO does not plan to publish this information for statistical use. However, sequence listing information will be published as part of the routine pre-grant publication of applications as well as issued patents.

17. Display of Expiration Date of OMB Approval

The form in this information collection will display the OMB Control Number and the expiration date of OMB approval.

18. Exception to the Certificate Statement

This collection of information does not include any exceptions to the certificate statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.