

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 2013)

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 13^{ter}.

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.

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

	Requirement	Statute	Rule
1	Sequence Listing in Application and Electronic 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 published sequence listings are 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 Quality Guidelines from Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for Fiscal Year 2001, apply to this information collection, and this information collection and its supporting statement comply with all applicable information quality guidelines, i.e. OMB and specific operating unit guidelines.

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

Table 2: Needs and Uses

	Item	Form #	Needs and Uses
1	Sequence Listing in Application (paper)	No Form Associated	<ul style="list-style-type: none"> 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 participate with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
2	Sequence Listing in Application (CD)	No Form Associated	<ul style="list-style-type: none"> 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. Used by the USPTO to participate with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
3	Electronic Sequence Listing in Application	No Form Associated	<ul style="list-style-type: none"> 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 participate with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
4	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e)	PTO/SB/93	<ul style="list-style-type: none"> 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 are also 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 may also 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.

Information technology system improvements can provide an opportunity to reduce the burdens associated with USPTO information collections. For example, the USPTO recognizes that it may be possible for it to revise the format by which an applicant makes a statement regarding the inclusion of a sequence listing in a patent application, and to modify how a pre-grant publication or patent references the presence of the sequence listing. Such revisions and modifications, however, would require significant changes to the USPTO's information technology systems (as well as regulatory changes), and, at present, are not the most effective use of available resources. The agency plans to revisit the information technology issue, as well as any associated adjustments to the rules of practice.

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 must also 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 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 does involve 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 (by 50%) for persons, small business concerns, or nonprofit organizations that qualify as small 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 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

A 60-Day *Federal Register* Notice was published on October 29, 2012 (77 Fed. Reg. 65537). The comment period ended on December 28, 2012. 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. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. The USPTO also meets regularly with groups from whom sequence information is collected, such as BIO, the Biotechnology subgroup of the American Intellectual Property Law Association, and the Biotechnology Institute.

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 25,250 responses per year for this collection, with approximately 27% of these responses submitted by small entities. Approximately 55% of the total responses for this collection will be submitted electronically.

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 six minutes (0.10 hours) to six 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 \$371 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the 2011 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 \$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.

Table 3: Burden Hour/Burden Cost to Respondents

	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate (\$/hr) (d)	Total Cost (\$/yr) (e) (c) x (d)
1	Sequence Listing in Application (paper)	6.00	8,500	51,000	\$163.50	\$8,338,500.00
2	Sequence Listing in Application (CD)	6.00	500	3,000	\$163.50	\$490,500.00
3	Electronic Sequence Listing in Application	6.00	14,000	84,000	\$163.50	\$13,734,000.00
4	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	0.10	2,250	225	\$122.00	\$27,450.00
	Totals	25,250	138,225	\$22,590,450.00

13. Total Annual (Non-hour) Cost Burden

The total annual (non-hour) respondent cost burden for this collection is calculated in Table 4 below. This collection has no capital start-up or recordkeeping costs.

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 \$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.
- 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.

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 \$5.60 (USPS Priority Mail, flat rate envelope) and that 9,000 sequence listings will be mailed to the USPTO per year.

Table 4: Annual (Non-hour) Cost Burden

Type of Cost	Estimated Annual Responses	Amount	Totals
Size fees under 37 CFR 1.16(s) and 1.492(j), large entity	250	\$960.00	\$240,000.00
Size fees under 37 CFR 1.16(s) and 1.492(j), small entity	200	\$480.00	\$96,000.00
Size fees for international applications	900	\$2,400.00	\$2,160,000.00
Total Fees	-----	-----	\$2,496,000.00
Postage for paper or CD sequence listing submissions	9,000	\$5.60	\$50,400.00
Total Postage	-----	-----	\$50,400.00
Total Annual (Non-hour) Cost Burden	-----	-----	\$2,546,400.00

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 \$18.20, and the average hourly rate of a GS-12, step 1 (\$35.88) and GS-13, step 1 (\$42.66) is currently \$39.27, which results in a weighted average hourly rate of \$32.25 and an estimated cost of \$41.93 per hour (\$32.25 with 30% (\$9.68) 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 cost of \$23.66 per hour (GS hourly rate of \$18.20 with 30% (\$5.46) added for benefits and overhead).

Table 5 calculates the burden hours and costs to the Federal Government for processing this information collection:

Table 5: Burden Hour/Burden Cost to the Federal Government

	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate (\$/hr) (d)	Total Cost (\$/yr) (e) (c) x (d)
1	Sequence Listing in Application (paper)	0.40	8,500	3,400	\$41.93	\$142,562.00
2	Sequence Listing in Application (CD)	0.40	500	200	\$41.93	\$8,386.00
3	Electronic Sequence Listing in Application	0.40	14,000	5,600	\$41.93	\$234,808.00
4	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	0.13	2,250	293	\$23.66	\$6,932.00
	Totals	25,250	9,493	\$392,688.00

15. Reasons for Changes in Burden from the Current Inventory

OMB previously approved this information collection in February 2010 with a total of 19,750 responses, 103,750 burden hours, and \$920,959 in annual (non-hour) costs. There have been no interim approvals.

Changes from the 60-Day *Federal Register* Notice to the Current Submission

The USPTO has updated the estimated postage cost for mailed submissions from \$5.15, as published in the 60-Day *Federal Register* Notice, to \$5.60 due to the USPS rate changes that are effective on January 27, 2013. Consequently, the total annual (non-hour) cost burden for this renewal has been revised from the \$2,542,350 published in the 60-Day *Federal Register* Notice to \$2,546,400.

Changes in Responses and Burden Hours from the Current Inventory

For this renewal, the USPTO estimates that the total annual responses will be 25,250 and the total annual burden hours will be 138,225, which is an increase of 5,500 responses and 34,475 burden hours from the currently approved burden for this collection. These increases are due to administrative adjustments from updated annual response estimates. There are no program changes.

Table 6a: Changes in Responses and Burden Hours from the Current Inventory

	Item	Currently approved responses	Updated responses	Change in responses (admin.)	Currently approved burden hours	Updated burden hours	Change in burden hours (admin.)
1	Sequence Listing in Application (paper)	3,450	8,500	5,050	20,700	51,000	30,300
2	Sequence Listing in Application (CD)	865	500	(365)	5,190	3,000	(2,190)
3	Electronic Sequence Listing in Application	12,935	14,000	1,065	77,610	84,000	6,390
4	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	2,500	2,250	(250)	250	225	(25)
	Totals	19,750	25,250	5,500	103,750	138,225	34,475

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

The total annual (non-hour) cost burden for this submission of \$2,546,400 is an increase of \$1,625,441 from the currently approved total of \$920,959. This increase is due to program changes and administrative adjustments.

Program changes

- Fees: Increased in part due to increases in size fee amounts from the previous renewal.
- Capital start-up: Removed costs associated with submitting CDs since blank media and padded envelopes are standard business supplies.
- Recordkeeping: Removed costs associated with retaining back-up copies of CDs and acknowledgment receipts from online submissions because keeping these items is a suggestion and not a requirement.

Administrative adjustments

- Fees: Increased in part due to increases in estimated responses that incur size fees.
- Postage: Increased due to increases in estimated number of mailed responses and increases in USPS postage rates since the previous renewal.

Table 6b: Changes in Annual (Non-hour) Costs from the Current Inventory

	Cost	Currently approved annual cost burden	Administrative adjustments	Program changes	Total change in costs	Updated annual cost burden
1	Fees	\$876,675.00	\$1,161,825.00	\$457,500.00	\$1,619,325.00	\$2,496,000.00
2	Capital start-up	\$11,225.00	\$0.00	(\$11,225.00)	(\$11,225.00)	\$0.00
3	Recordkeeping	\$11,700.00	\$0.00	(\$11,700.00)	(\$11,700.00)	\$0.00
4	Postage	\$21,359.00	\$29,041.00	\$0.00	\$29,041.00	\$50,400.00
	Totals	\$920,959.00	\$1,190,866.00	\$434,575.00	\$1,625,441.00	\$2,546,400.00

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.