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
2022

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Patent applications that contain nucleotide and/or amino acid sequence disclosures falling within the definitions of 37 CFR 1.821(a) (for applications filed on or before June 30, 2022) or 37 CFR 1.831 (for applications filed on or after July 1, 2022) must include, as a separate part of the application disclosure, a copy of the sequence listing in accordance with the requirements in 37 CFR 1.821-1.825 or 37 CFR 1.831-1.835, respectively. Applicants may submit sequence listings for both U.S. and international patent applications. Submissions of sequence listings in international applications are governed by Patent Cooperation Treaty (PCT) Rules 5.2 and 13*ter*, as well as the PCT Administrative Instructions, Annex C.

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

Sequence listings in applications filed on or before June 30, 2022 may be submitted via the USPTO patent electronic filing system as an ASCII text file or as a Portable Document Format (PDF) file. For U.S. applications filed on or before June 30, 2022, 37 CFR 1.821(c) permits all modes of submission: paper, read-only optical disc, or electronic filing via the USPTO patent electronic filing system. Sequence listings for international applications may only be submitted on paper or through the USPTO patent electronic filing system. Sequence listings that are too large to be filed electronically though the USPTO patent electronic filing systemmay be submitted on read-only optical disc.

This information collection also accounts for the requirement under 37 CFR 1.821(e)(1) or 1.821(e)(2) that a copy of the sequence listing submitted pursuant to 37 CFR 1.821(c)(2) or (c)(3) must also be submitted in computer readable form (CRF) in accordance with the requirements of 37 CFR 1.824. Under 37 CFR 1.821(e)(1) or 1.821(e)(2), applicants who submit their sequence listings on paper or as a PDF via the

USPTO patent electronic filing systemmust submit a copy of the sequence listing in CRF with a statement indicating that the CRF copy of the sequence listing is identical to the paper or PDF copy provided under 37 CFR 1.821(c)(3) or 1.821(c)(2), respectively. Applicants may submit the CRF copy of the sequence listing to the USPTO via the USPTO patent electronic filing system, or on read-only optical disc or other acceptable media as provided in 37 CFR 1.824. If a new application is filed via the USPTO patent electronic filing systemwith an ASCII text file sequence listing that complies with the requirements of 37 CFR 1.824(a)(1)–(5) and (b), and the applicant has not filed a sequence listing on paper or as a PDF file, no separate text file is required.Therefore, no associated statement regarding both copies being identical would be required. Similarly, if a new application is filed with an ASCII text file sequence listing on read-only optical that complies with the requirements of 37 CFR 1.824(a)(1)–(5) and 37 CFR 1.52(e), the single read-only optical disc is the CRF, and no additional submission is required.

Sequence listings in applications filed on or after July 1, 2022 must be submitted in XML format per 37 CFR 1.831, which was recently implemented to achieve alignment with World Intellectual Property Office Standard ST.26 (WIPO Standard ST.26) (Standard for Presentation of Nucleotide and Amino Acid Sequence Listings Using eXtensible Markup Language (XML) in Patent Applications To Implement WIPO Standard ST.26; Incorporation by Reference, 87 FR 30806, 5/20/22, effective July 1, 2022). These submissions may be made electronically via the USPTO patent electronic filing system as an XML file not exceeding 100MB without file compression, or as an XML file on a read-only optical disc in accordance with 37 CFR 1.834(b)-(c).

One item, Request for Transfer of a Computer Readable Form under 37 CFR 1.821(e), has been removed from this information collection. This item is no longer part of this collection's process per a recent rulemaking (Electronic Submission of a Sequence Listing, a Large Table, or a Computer Program Listing Appendix in Patent Applications; 86 FR 57035, 10/14/2021, effective November 15, 2021).

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

Table 1: Information Requirements

Item No.	Requirement	Statute	Regulation
1	Sequence Listing in Application	35 U.S.C. § 22	37 CFR 1.821-1.825 (applications filed on or before June 30, 2022), 37 CFR 1.831-1.835 (applications filed on or after July 1, 2022)

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The USPTO uses the sequence listings during the examination process to determine the patentability of the invention claimed in the application. The USPTO also uses the sequence listings for pre-grant publication of applications and issued patents. The USPTO enters the information in the CRF into the USPTO's database for searching and printing nucleotide and amino acid sequences. Sequence listings are publicly searchable on the USPTO's website upon application publication and/or issuance. Copies of sequence listings from issued patents and pre-grant patent application publications are forwarded to the National Center for Biotechnology Information for inclusion in their sequence database. Applicants use sequence listings when preparing both national and international patent applications that disclose nucleotide and/or amino acid sequences to provide a written description of the invention and to distinguish the claimed subject matter from the prior art.

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

Item No.	Form/ Function	Form #	Needs and Uses
1	Sequence Listing in Application	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 the invention claimed in an application. • Used by the USPTO to support publication of patent applications and issued patents.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

For U.S. applications filed on or before June 30, 2022, applicants may submit sequence listings on paper, read-only optical disc, or electronically through the USPTO patent electronic filing system as a text file or PDF. Due to PCT guidelines, sequence listings for international applications may not be submitted on read-only optical disc, except for oversized listings that are too large to submit online (more detail below). Submissions on read-only optical disc must follow the guidelines specified in 37 CFR 1.52(e). Applicants who submit their sequence listings on paper or as a PDF via the USPTO patent electronic filing system 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.

For U.S. applications filed on or after July 1, 2022, applicants may submit sequence listings as XML files transmitted electronically through the USPTO patent electronic filing system where the file does not exceed 100MB without compression, or as larger XML files submitted on read-only optical disc.

Filers submitting sequence listings to the USPTO electronically through the USPTO patent electronic filing system upload the listings using the secure the USPTO patent electronic filing system interface.

The USPTO patent electronic filing system 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 listing files that exceed 100 megabytes may not be submitted online via the USPTO patent electronic filing system. These oversized sequence listings should be copied onto read-only optical disc for submission to the USPTO by mail. Customers are advised to keep a back-up copy of the read-only optical disc and transmittal information for their own records. The acceptance of read-only optical discs 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.”

For applications filed on or before June 30, 2022, 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. The PatentIn software may be downloaded from the USPTO website, 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. For applications filed on or after July 1 2022, applicants may use WIPO Sequence, provided by WIPO, to author and validate sequence listings in XML format.

For CRF copies submitted to the USPTO, the data format is checked for compliance with the applicable regulations 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 (that is, 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 website (http://seqdata.uspto.gov). Shorter sequence listings are available through the standard patent and application search systems on the USPTO website.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

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.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

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 (see 37 CFR 1.29 for micro entity status). 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. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

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. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

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

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The 60-Day Notice was published in the *Federal Register* on June 7, 2022 (87 FR 34667). The comment period ended on August 8, 2022. No comments were received.

The USPTO has long-standing relationships with groups who frequently communicate their views on information collections, including the American Bar Association (ABA), American Intellectual Property Law Association (AIPLA), inventor associations, patent bar associations, independent inventor groups, and users of our public search facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. There have been no comments or concerns expressed by these or similar organizations concerning the time to provide the information required under this program

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

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

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Confidentiality of patent applications is governed by statute (35 U.S.C. § 122) and regulation (37 CFR 1.11 and 1.14). Upon publication of an application or issuance of a patent, the entire patent application file is made available to the public (subject to provisions for providing only a redacted copy of the file contents). Therefore, the information collected by this information collection will necessarily be available to the public when it is either filed in a published application or issued patent, or when it is filed in an application that is later published or issued as a patent.

The Privacy Act of 1974 (P.L. 93-579) requires that individuals submitting these items to USPTO be given certain information in connection with that submission. The USPTO collects this information under authority of 37 CFR 1.28 and 1.29. The purpose of the system is to carry out the duties of the USPTO to grant and issue patents.

Categories of individuals covered by the system include applicants for patent, including inventors, legal representatives for deceased or incapacitated inventors, and other persons authorized by law to make applications for patent. The information in this system of records is used to manage all applicant records including name, citizenship, residence, post office address, and other information pertaining to the applicant's activities in connection with the invention for which a patent is sought.

The information is protected from disclosure to third parties in accordance with the Privacy Act. However, routine uses of this information may include disclosure to the following: to law enforcement and investigation in the event that the system of records indicates a violation or potential violation of law; to a Federal, state, local, or international agency, in response to its request; to an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law; to non-federal personnel under contract to the agency; to a court for adjudication and litigation; to the Department of Justice for Freedom of Information Act assistance; to members of congress working on behalf of an individual; to the Office of Personnel Management for personnel research purposes; to National Archives and Records Administration for records management activities; and to the Office of Management and Budget for legislative coordination and clearance. Failure to provide any part of the requested information may result in an inability to process submissions.

The applicable Privacy Act System of Records Notice for this information is COMMERCE/PAT-TM-7 Patent Application Files, available at Federal Register /Vol. 78, No. 61 / Friday, March 29, 2013 /Notices 19243. https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

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

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.**
- **Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information.**

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 28,550 responses per year from 9,550 respondents for this information collection, with approximately 25% of these responses submitted by small entities.

  The USPTO estimates that approximately 99% of the annual responses for this collection will be submitted electronically via the USPTO patent electronic filing system, which customers may access through the USPTO website.

- **Burden Hour Calculation Factors**
  The USPTO estimates that it takes the public approximately 6 hours, depending on the complexity of the situation and item, to gather the necessary information, prepare the appropriate document, and submit the information to the USPTO. Using these burden factors, USPTO estimates that the total respondent hourly burden for this information collection is 171,600 hours per year.

- **Cost Burden Calculation Factors**

The USPTO uses a professional rate of $435 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the

2021 *Report of the Economic Survey*, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA).

Using these hourly rates, the USPTO estimates that the total respondent cost burden for this information collection is $74,589,885 per year.

Table 3: Total Burden Hours and Hourly Costs to Private Sector Respondents

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate[1] ($/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Sequence Listing in Application	9,500	3	28,500	6	171,000	$435	$74,385,000

Table 4: Total Burden Hours and Hourly Costs to Individuals or Households Respondents

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate[2] ($/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Sequence Listing in Application	50	1	50	6	300	$435	$130,500

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of**

[1] 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); y. The USPTO uses the mean IP billing rate for attorneys in private firms which is $435 per hour. (https://www.aipla.org/home/news-publications/economic-survey; pg F-27).

[2] Ibid.

purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

With fee costs totaling $1,481,290 and postage costs totaling $2,646, the USPTO estimates that the total annual non-hourly cost burden for this collection will amount to $1,483,936.

Filing Fees

In accordance with 35 U.S.C. 41(a)(1)(G), the USPTO charges a fee for submitting a sequence listing as part of a U.S. patent application or as part of an international patent application entering the U.S. national stage if the sequence listing (i) is not filed via the USPTO patent electronic filing system or on an electronic medium in compliance with 37 CFR 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) for U.S. patent applications and 1.492(j) for international patent applications entering the national stage, if the patent application inclusive of sequence listings filed on paper or on a non-compliant electronic medium exceeds 100 pages, the application size fee is $420 ($210 for small entities, $105 for micro entities) for each additional 50 pages or fraction thereof. The average length of a sequence listing filed on paper or in PDF format is 150 pages, which results in an average total size fee of $1260 ($630 for small entities, $315 for micro entities) for applications that are 100 pages long prior to adding the sequence listing.

As a Receiving Office under the Patent Cooperation Treaty, the USPTO collects a basic international filing fee for each international application it receives. The basic international filing fee only covers the first 30 pages of the international application. For each additional application page in excess of 30, a size fee of $16 is added to the basic international filing fee. The average length of a sequence listing in an international application filed on paper or in PDF format is 150 pages. As a result, a paper- or PDF-filed international application including a sequence listing incurs an estimated $2,400 size fee when the application already includes 30 pages prior to adding the sequence listing.

The USPTO charges a fee for the handling of mega sequence listings. There are two tiers of fees related to different sequence listing sizes: one tier for file sizes between 300 MB and 800 MB, and one tier for file sizes greater than 800 MB.

The USPTO also charges a Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* to encourage timely filing of sequence

listings in international applications and to facilitate the effective administration of the patent system.

Table 5: Filing Fee Costs

Item No.	Item	Estimated Annual Responses (a)	Filing Fee ($) (b)	Non-hourly Cost Burden (a) x (b) = (c)
1	Size fees under 37 CFR 1.16(s) and 1.492(j), undiscounted entity	130	$1,260	$163,800
1	Size fees under 37 CFR 1.16(s) and 1.492(j), small entity	65	$630	$440,950
1	Size fees under 37 CFR 1.16(s) and 1.492(j), micro entity	25	$315	$7,875
1	Size fees for international applications	420	$2,400	$1,008,000
1	Submission of sequence listings of 300MB to 800MB (undiscounted entity)	30	$1,060	$31,800
1	Submission of sequence listings of 300MB to 800MB (small entity)	30	$530	$15,900
1	Submission of sequence listings of 300MB to 800MB (micro entity)	10	$265	$2,650
1	Submission of sequence listings of more than 800MB (undiscounted entity)	2	$10,500	$21,000
1	Submission of sequence listings of more than 800MB (small entity)	1	$5,250	$5,250
1	Submission of sequence listings of more than 800MB (micro entity)	1	$2,625	$2,625
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* (undiscounted entity)	215	$320	$68,800
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* (small entity)	700	$160	$112,000
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* (micro entity)	8	$80	$640
	Totals	**- - -**	**- - -**	**$1,481,290**

Postage

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be $9.25. The

USPTO estimates that 1% of sequence listings will be submitted by mail, resulting in 286 mailed submissions. Therefore, the USPTO estimates the total mailing costs for this information collection at $2,646.

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

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 $21.84, and the average hourly rate of a GS-12, step 1 ($43.04) and GS-13, step 1 is currently ($51.18). These rates produce a weighted average hourly rate of $38.70, which results in a fully-loaded hourly rate of $50.31 per hour ($38.70 with 30% ($11.61)) added for benefits and overhead for processing the sequence disclosures.

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 Annual Responses (a)	Estimated Response Time (Hours) (b)	Estimated Annual Burden Hours (a) x (b) = (c)	Rate ($/hr) (d)	Total Cost ($/yr) (c) x (d) = (e)
1	Sequence Listing in Application	28,850	0.40	11,540	$50.31	$580,577
	Totals	**28,850**	**- - -**	**11,540**	**- - -**	**$580,577**

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	28,550	0	0	4,700	0	23,850
Annual Time Burden (Hr)	171,300	0	0	37,345	0	133,955
Annual Cost Burden ($)	1,483,936	0	0	220,463	0	1,263,473

Change due to Adjustment in Agency Estimate

The total number of respondents and time burden have increased; increases in the number of responses (+4,700) and burden hours (+37,345) are due to the increase in response items in this information collection.

The estimated cost burden has increased (+220,463) due to the increase in the estimated number of responses.

16. **For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.**

The USPTO does not plan to publish this information for statistical use. However, patent and trademark assignment records are available to the public at the USPTO Public Search Facilities and on the USPTO Web site.

17. **If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

There are no forms in this information collection on which to display the OMB Control Number and the expiration date of OMB approval.

18. **Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."**

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

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.