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

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 are also disclosed as part of the published patent application or issued patent. Sequence listings that are extremely long (files larger than 600K or approximately 300 printed pages) are published only in electronic form and are available to the public on the USPTO sequence data Web page.

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 is proposing to add a new form to this collection, 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 PCT are covered under OMB Control Number 0651-0021.

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

Table 1: Information Requirement for Sequence Disclosures

Requirement	Statute	Rule
Sequence Listing in Application and Electronic Sequence Listing in Application	35 U.S.C. § 22	37 CFR 1.821-1.825
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. In addition, the sequences are 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. 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 also 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 comply with all applicable information quality guidelines, i.e. OMB and specific operating unit guidelines.

This proposed collection of information will result in information that will be collected, maintained, and used in a way consistent with all applicable OMB and 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 of Information Collected for Sequence Disclosures

Item	Form #	Needs and Uses
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 participate with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
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. • 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.
Electronic Sequence Listing in Application (EFS-Web)	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 participate with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
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 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 recent changes in 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 online through EFS-Web, the USPTO's web-based patent application and document submission system that allows customers to file patent applications and associated documents electronically 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 public training sessions on how to use the software. Training is available in-person and online via Web cast. 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 viewing or download through the Publication Site for Issued and Published Sequences (PSIPS) on the USPTO Web site. 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 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 has developed a new 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

The 60-Day Notice was published in the *Federal Register* on August 11, 2009 (74 Fed. Reg. 40163). The comment period ended on October 13, 2009. Five commenters (including individual patent practitioners, industry, and the general public) responded to the August 11, 2009 60-Day Notice. The USPTO's responses to the comments follow (comments that are generally favorable are not discussed):

Comment 1: Four commenters indicated that the USPTO has underestimated the time and level of skill required to gather the necessary information, prepare the sequence listing, and submit it to the USPTO.

Response: The USPTO notes the concerns expressed by the commenters regarding the time and level of skill required to gather the necessary information, prepare the sequence listing, and submit it to the USPTO. In response to those concerns, the USPTO in this Supporting Statement has revised its estimate for the amount of time and level of skill required to gather the necessary information, prepare the sequence listing, and submit it to the USPTO, as shown in greater detail at Table 3 below.

Comment 2: One commenter noted the possibility of improving the ability of PatentIn to import sequences from a FASTA or other standard format. The commenter also recommended that the USPTO work with the National Center for Biotechnology Information (NCBI) on sequence listing entry.

Response: The USPTO is grateful for the comments regarding PatentIn and sequence listing entry. The USPTO regularly evaluates all options for improving PatentIn and sequence listing entry, and will take the present comments under advisement.

Comment 3: One commenter suggested that the fees charged for sequence listings should be based on the number of sequences, number of characters, or number of pages.

Response: 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 $270 (or $135 for small entities) for each additional 50 pages or fraction thereof.

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 $13 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.

Comment 4: One commenter indicated that the primary focus on collection of sequence information appears to be on "coded amino acid sequences," made by translation of mRNA, since any sequences containing D-amino acids are specifically excluded and any "non-coded amino acid" is listed as "Xaa," with its identity only disclosed in the features section of the listing. The commenter further stated that the current rules are both underinclusive, because they do not capture any information that can be meaningfully searched as to the identity of "non-coded amino acids," and overinclusive by requiring disclosure of amino acid sequences made by chemically synthetic means. The commenter concluded that the information collected is of little or no practical utility except in the case of sequences consisting solely of "coded amino acids."

Response: The international standard for sequence listings was established based upon the conventions used in public databases with regard to residue abbreviations in sequences. The current rules, 37 CFR 1.821 - 1.825, are consistent with World Intellectual Property Organization (WIPO) Standard ST.25 (signed in 1998 and effective July 1, 1998), and sequence listings prepared in accordance with those rules generally will be acceptable in all countries which adhere to that standard. One response to comments in the "Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Disclosures," 63 Fed. Reg. 29620-29643 (June 1, 1998), indicated that sections 1.821 – 1.825 do not require any information to be disclosed in the form of a sequence, but rather require a particular format whenever information is presented in the form of a sequence. The general public is assured that patents which contain sequence information contain the sequence information in the sequence listing and the sequences are available in a computer accessible form. The June 1, 1998 publication further indicated that because the sequence databases did not include D-amino acids in sequences at that time, submission of those sequences containing D-amino acids was not made mandatory; however, voluntary submissions of protein sequences containing D-amino acids would be accepted.

A search of a sequence containing an amino acid listed as "Xaa," where the modified or unusual amino acid is described in the features section of the sequence listing, can potentially produce references useful in the determination of whether a claimed sequence may be considered obvious. Many synthetic sequences containing unusual residues are homologs (similar sequences) or analogs of natural sequences or fragments of natural sequences (template). A search query of the template may identify prior art that discloses the template sequence and discusses such homologs or analogs.

Comment 5: One commenter recommended that the USPTO Checker software be updated to alert users to the same potential errors that are caught by the Office's internal sequence checking software.

Response: The USPTO thanks the commenter for his recommendation regarding the USPTO Checker software. However, experience over the past two years reveals a very limited number of times in which errors were caught by the Office's internal sequence checking software that were not caught by Checker. In addition, the USPTO provides User Notes for Checker at the Web page http://www.uspto.gov/patents/resources/tools/checker/chkrnote.jsp. Experience over the past two years reveals that a majority of the errors involving Checker could have been avoided by familiarity with the provided User Notes.

Comment 6: One comment indicated that additionally requested information, such as the name of the organism and repetition of client identification and inventor names is not necessary.

Response: A sequence listing is stored and published in a database that is separate from the remainder of the application; therefore, the referenced identifying information is a necessary part of the listing.

Comment 7: One comment indicated that a sequence listing should be required only for sequences that are claimed or substantially likely to be claimed.

Response: As noted in the response to comments in the "Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Disclosures," 63 Fed. Reg. 29620-29643 (June 1, 1998), sections 1.821 – 1.825 do not require any information to be disclosed in the form of a sequence, but rather require a particular format whenever information is presented in the form of a sequence. Requiring the particular format for both unclaimed and claimed information presented in the form of a sequence serves the important purpose of building the Office's prior art database.

Comment 8: One comment indicated that a statement indicating that the paper copy and the electronic copy of the sequence listing are identical should not be required, but rather a checkbox could be added to the transmittal letter.

Response: When an application is filed electronically via EFS-Web with the sequence listing in text format, the sequence listing serves both as part of the application and as the computer readable form for search purposes. No statement is required under these circumstances. When an application is filed in paper, an indication that the sequence listings are identical is still necessary. The Office will take under advisement the suggestion to provide for a checkbox.

Comment 9: One comment indicated that the sequence listing should be considered part of the specification, rather than requiring a preliminary amendment or incorporation by reference.

Response: The sequence listing is considered part of the application as originally filed. The incorporation by reference statement is needed to notify the public that a sequence listing is part of the application because the Office does not publish the full text of all sequence listings for patents or patent application publications.

Comment 10: One comment indicated that an easier way to list unusual amino acids or nucleotides should be provided.

Response: The international standard for sequence listings was established based upon the conventions used in public databases with regard to residue abbreviations in sequences. The World Intellectual Property Organization (WIPO) Standard ST.25 was signed in 1998, became effective July 1, 1998, and has not been changed since that time. The current U.S. rules are consistent with that standard and will not be changed until such time as ST.25 is modified.

Comment 11: One comment indicated that a better software program should be provided for preparation of sequence listings that could accept both three and one letter amino acid codes.

Response: This change will be made once funds are available for a software update.

Comment 12: One comment indicated that the patent examiner should explain how to correct errors in a sequence listing, and if the correction is simple, correct it by examiner's amendment.

Response: Sequence listings are reviewed for compliance prior to receipt of the application by the examiner. An error report is provided together with the notice to comply with the sequence requirements. Correction cannot be made simply by examiner's amendment, since a corrected electronic copy is required for search and publication purposes.

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. The disclosure of the invention in the application is the quid pro quo for the property right conferred by the patent grant and the very means by which the patent statute achieves its constitutional objective of "promot[ing] the progress of science and useful arts." The prosecution history contained in the application file is critical for determining the scope of the property right conferred by a patent grant.

11. Justification for Sensitive Questions

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

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 19,750 responses per year for this collection.

- **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.

- **Cost Burden Calculation Factors**
  In 2009 the Committee on Economics of Legal Practice of the American Intellectual Property Law Association published a report that summarized the results of a survey with data on hourly billing rates. The professional rate of $325 per hour is the median rate for attorneys in private firms as published in that report. The USPTO estimates that a sequence listing will take approximately five hours of paraprofessional time at an estimated rate of $100 per hour and one hour of attorney time at $325 per hour, for a weighted average rate of $137.50 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 $100 per hour. These are fully-loaded hourly rates.

Table 3: Burden Hour/Burden Cost to Respondents for Sequence Disclosures

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/yr) (e) (c) x (d)
Sequence Listing in Application (paper)	6.00	3,450	20,700	$137.50	$2,846,250.00
Sequence Listing in Application (CD)	6.00	865	5,190	$137.50	$713,625.00
Electronic Sequence Listing in Application (EFS-Web)	6.00	12,935	77,610	$137.50	$10,671,375.00
Request for Transfer of a Computer Readable Form under 37 CFR 1.821(e) (PTO/SB/93)	0.10	2,500	250	$100.00	$25,000.00
Totals	. . . . .	**19,750**	**103,750**	. . . .	**$14,256,250.00**

The USPTO estimates that approximately 65% of the total responses for this collection will be submitted electronically through EFS-Web.

13. Total Annualized Cost Burden

There are no maintenance costs associated with this collection. The USPTO provides free software for creating and validating the format of sequence listings prior to submission. However, this collection does have annual (non-hour) costs in the form of fees, capital start-up costs, recordkeeping costs, and postage costs.

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 $270 (or $135 for small entities) for each additional 50 pages or fraction thereof. The USPTO estimates that approximately 120 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 $810, and approximately 95 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 $405, for a total of $135,675 per year.

As a Receiving Office, the USPTO collects the international filing fee for each international application it receives. The basic international filing fee only covers the first 30 pages of the international application. As a result, a $13 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 $1,950 if the international application were already at least 30 pages long without the listing. The USPTO estimates that approximately 380 of the 3,450 sequence listings filed per year on paper or in PDF format will be for international applications, for a total of $741,000 per year in page fees. **Therefore, this collection has a total of $876,675 in fees per year.**

There are capital start-up costs associated with submitting sequence listings and CRF copies to the USPTO on CD. Applicants who submit sequence listings on CD must submit two copies of the CD (or three copies for international applications) along with a transmittal letter stating that the copies are identical. This process requires additional supplies, including blank recordable CD media and padded envelopes for shipping. The USPTO estimates that the cost of these supplies will be approximately $3 per CD submission and that it will receive approximately 865 CD submissions per year, for a total of $2,595. In addition, customers who submit sequence listings on paper or CD must also submit a separate CRF copy of the listing, which may be submitted on CD. The USPTO estimates that it will receive approximately 4,315 CRF copies for paper and CD sequence listings at an estimated cost of $2 per copy, for a total of $8,630. **Therefore, this collection has total capital start-up costs of $11,225 per year.**

Applicants who submit sequence listings on CD may also incur recordkeeping costs. The USPTO advises applicants to retain a back-up copy of CD submissions and associated documentation for their records. The USPTO estimates that it will take applicants five minutes to produce a back-up CD copy and two minutes to print copies of documentation, for a total of seven minutes (0.12 hours) to make a back-up copy of the CD submission. The USPTO estimates that approximately 865 CD submissions will be received per year, for a total of 104 hours for making back-up copies. The USPTO expects that these back-up copies will be prepared by paraprofessionals at an estimated rate of $100 per hour, for a recordkeeping cost of $10,400 per year.

There are also recordkeeping costs associated with submitting sequence listings online using EFS-Web. The USPTO recommends that customers print and retain a copy of the acknowledgment receipt after a successful online submission. The USPTO estimates that it will take five seconds (0.001 hours) to print a copy of the acknowledgment receipt and that approximately 12,935 sequence listings per year will be submitted via EFS-Web, for a total of approximately 13 hours per year for printing this receipt. The USPTO expects that these receipts will be printed by paraprofessionals at an estimated rate of $100 per hour, for a recordkeeping cost of $1,300 per year. **Therefore, this collection has total recordkeeping costs of $11,700 per year associated with retaining copies of CDs and acknowledgment receipts.**

Customers may incur postage costs when submitting a sequence listing to the USPTO by mail. Mailed submissions may include the sequence listing on either paper or CD, the CRF copy of the listing on CD, and a transmittal letter containing the required identifying

information. The USPTO estimates that the average postage cost for a paper or CD sequence listing submission will be $4.95 and that 4,315 sequence listings will be mailed to the USPTO per year. **Therefore, this collection has total postage costs of $21,359 per year.**

The total annual (non-hour) respondent cost burden for this collection in the form of fees ($876,675), capital start-up costs ($11,225), recordkeeping costs ($11,700), and postage costs ($21,359) is estimated to be $920,959 per year.

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 $17.77, and the average hourly rate of a GS-12, step 1 ($35.03) and GS-13, step 1 ($41.65) is currently $38.34, which results in a weighted average hourly rate of $31.48 for the USPTO staff processing the sequence disclosures. When 30% is added to account for a fully-loaded hourly rate (benefits and overhead), the hourly rate for processing these submissions is $40.92 ($31.48 + $9.44).

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. The hourly rate for a GS-6, step 1 is currently $17.77. When 30% is added to account for a fully-loaded hourly rate (benefits and overhead), the hourly rate for processing these submissions is $23.10 ($17.77 + $5.33).

Table 4 calculates the burden hours and costs to the Federal Government for processing this information collection:

Table 4: Burden Hour/Burden Cost to the Federal Government for Sequence Disclosures

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/yr) (e) (c) x (d)
Sequence Listing in Application (paper)	0.40	3,450	1,380	$40.92	$56,470.00
Sequence Listing in Application (CD)	0.40	865	346	$40.92	$14,158.00
Electronic Sequence Listing in Application (EFS-Web)	0.40	12,935	5,174	$40.92	$211,720.00
Request for Transfer of a Computer Readable Form under 37 CFR 1.821(e) (PTO/SB/93)	0.13	2,500	325	$23.10	$7,508.00
Totals	.....	**19,750**	**7,225**	.....	**$289,856.00**

15. Reason for Change in Burden

Summary of Changes Since the Previous Renewal

This information collection was previously approved in December 2006 with a total of 15,382 responses and 17,297 burden hours per year.

For this renewal, the USPTO estimates that the total annual responses will be 19,750 and the total annual burden hours will be 103,750, which is an increase of 4,368 responses and 86,453 burden hours from the currently approved burden for this collection. This increase in burden hours is due to both program changes and administrative adjustments. In addition, the USPTO estimates that the proportion of responses submitted electronically (using EFS-Web) will increase from approximately 15% to 65%.

The total annual (non-hour) cost burden for this renewal of $920,959 is a decrease of $3,364,879 from the currently approved total of $4,285,838 in annual costs for this collection. This decrease in annual costs is due to both program changes and administrative adjustments.

Changes from the 60-Day Notice

Since the 60-Day Notice was published, the USPTO has decided to revise the time estimates and respondent cost burden for sequence listing responses, including paper, CD, and electronic submissions. The USPTO has revised the estimated time for all types of sequence listing submissions to six hours per response, an increase from the estimates in the 60-Day Notice of one hour and 20 minutes (paper), 15 minutes (CD), and ten minutes (EFS-Web). In addition, the USPTO has revised the estimated hourly cost burden for sequence listing responses from the paraprofessional rate of $100 per hour to a rate of $137.50 per hour, which is the weighted average of five hours of paraprofessional time and one hour of attorney time as noted in Section 12 of this Supporting Statement.

As a result of these changes, the total estimated burden hours for this collection have been increased from what was reported in the 60-Day Notice, from 7,254 to 103,750 burden hours. In addition, the total estimated respondent cost burden has been increased from $725,400 to $14,256,250 due to the increase in total estimated burden hours and increased hourly rate for respondents preparing sequence listings.

Change in Respondent Cost Burden

This collection was previously approved in December 2006 with 17,297 burden hours and an estimated total respondent cost burden of $1,556,730. That submission used an estimated rate of $90 per hour for paraprofessionals preparing the sequence listings. For this renewal, the estimated rate for paraprofessionals has been updated to $100 per hour and the hourly cost burden for preparing sequence listings has been updated to include a mixture of both paraprofessionals at an updated rate of $100 per hour and attorneys at a

rate of $325 per hour, for a weighted average rate of $137.50 per hour. The total burden hours for this renewal attributed to sequence listings has also increased to 103,500 due to overall increases in filings and an increase in the estimated time per response to six hours for all sequence listings. The 103,500 hours for this renewal attributed to sequence listings at the revised rate of $137.50 per hour yield a respondent cost burden of $14,231,250. The addition of the Request for Transfer of a CRF adds $25,000 in respondent cost burden. Therefore, this renewal has a total respondent cost burden of $14,256,250, which is an increase of $12,699,520 from the total respondent cost burden reported in the 2006 submission. This increase is due to the overall increase in the total burden hours for this collection and increases in the estimated hourly rates for respondents.

Changes in Responses and Burden Hours

For this renewal, the USPTO estimates that the annual responses for this collection will increase by 4,368, from 15,382 to 19,750 responses per year, and that the total burden hours for this collection will increase by 86,453, from 17,297 to 103,750 hours per year. This increase in burden hours is due to both program changes and administrative adjustments, as follows:

- The USPTO is adjusting the estimated annual responses for paper sequence listings to 3,450, which is a decrease of 8,062 from the previous estimate of 11,512. However, the USPTO has also revised the time estimate for preparing a paper sequence listing submission, increasing the estimate from one hour and 20 minutes to six hours per response. **Therefore, this collection takes a burden increase of 5,389 hours as an administrative adjustment.**

- The USPTO estimates that the annual responses for CD sequence listings will decrease by 735, from 1,600 to 865, due to expected decreases in filings and recent changes to PCT guidelines eliminating the submission of sequence listings on CD as part of an application filed on paper. However, the USPTO has also revised the time estimate for preparing a CD submission, increasing the estimate from one hour to six hours per response. **Therefore, this collection takes a net burden increase of 3,590 hours, with a decrease of approximately 200 hours as a program change being offset by an increase of 3,790 hours as an administrative adjustment.**

- The USPTO is adjusting the estimated annual responses for sequence listings filed electronically to 12,935, which is an increase of 10,665 from the previous estimate of 2,270. The USPTO has also revised the time estimate for preparing an electronic sequence listing submission, increasing the estimate from ten minutes to six hours per response. **Therefore, this collection takes a burden increase of 77,224 hours as an administrative adjustment.**

- The USPTO estimates that 2,500 Requests for Transfer of a CRF (PTO/SB/93) will be submitted per year. The USPTO is proposing to add this item to the collection.

Therefore, this collection takes a burden increase of 250 hours as a program change.

In sum, the decrease in paper and CD filings is offset by an increase in electronic filings using EFS-Web, adjustments to time estimates for all sequence listing responses, and the addition of the Request for Transfer of a CRF. **Therefore, this information collection has a total burden increase of 86,453 hours, with a net increase of 50 hours due to program changes and an increase of 86,403 hours due to administrative adjustments.**

Changes in Annual (Non-hour) Costs

For this renewal, the USPTO estimates that the total annual (non-hour) costs for this collection will decrease by $3,364,879, from $4,285,838 to $920,959 per year. The decrease in total annual (non-hour) costs is due to both program changes and administrative adjustments, as follows:

- This collection is currently approved with $4,184,250 in fees associated with submitting a sequence listing. For this renewal, the USPTO estimates that these fees will be $876,675, a decrease of $3,307,575, due to several factors:

  Fees for sequence listings submitted in proper text format on CD have been eliminated, **for a decrease of $960,000 from the currently approved collection as a program change.**

  Page fees for paper sequence listings for PCT applications have increased from $12 per page to $13 per page, but decreases in the estimated number of paper filings result in an overall decrease of $2,067,000 from the currently approved collection, with **an increase of $57,000 as a program change offset by a decrease of $2,124,000 as an administrative adjustment.**

  Size fees for applications that include lengthy sequence listings have increased from $250 ($125 for small entities) to $270 ($135 for small entities) for each 50 pages past 100, but decreases in the estimated number of paper filings result in an overall decrease of $280,575 from the currently approved collection, with **an increase of $10,050 as a program change offset by a decrease of $290,625 as an administrative adjustment.**

- This collection is currently approved with $31,024 in capital start-up costs for the supplies for producing and submitting sequence listings on CD, such as blank recordable media and shipping envelopes. For this renewal, the USPTO is revising the estimated capital start-up costs to $11,225 due to the elimination of CD sequence listing filings for paper PCT applications and expected overall decreases in paper and CD sequence listing filings (which also reduces the number of CRF copies submitted on CD). **Therefore, this collection takes a burden decrease of**

$19,799 in capital start-up costs, with a decrease of $1,000 as a program change and a decrease of $18,799 as an administrative adjustment.

- This collection is currently approved with a total of $17,280 in recordkeeping costs associated with keeping back-up copies of CD submissions. For this renewal, the USPTO estimates that these recordkeeping costs will decrease to $10,400 per year due to the elimination of CD sequence listing filings for paper PCT applications and expected overall decreases in CD filings. The estimated hourly rate for paraprofessionals making back-up CD copies has also increased from $90 to $100. **Therefore, this collection takes a burden decrease of $6,880 in recordkeeping costs, with a decrease of $2,160 as a program change and a decrease of $4,720 as an administrative adjustment.**

- This collection is currently approved with a total of $180 in recordkeeping costs associated with retaining acknowledgment receipts for electronic submissions of sequence listings. For this renewal, the USPTO estimates that these recordkeeping costs will increase to $1,300 per year due to expected overall increases in electronic filing and the increase in estimated hourly rate from $90 to $100 for paraprofessionals retaining the receipts. **Therefore, this collection takes a burden increase of $1,120 in recordkeeping costs as an administrative adjustment.**

- This collection is currently approved with a total of $53,104 in postage costs associated with submitting paper and CD sequence listings to the USPTO by mail. For this renewal, the USPTO estimates that the total postage costs will decrease to $21,359 per year due to the elimination of CD sequence listing filings for paper PCT applications and expected overall decreases in paper and CD filings, despite an increase in the estimated postage cost from $4.05 to $4.95 per submission. **Therefore, this collection has a burden decrease of $31,745 in postage costs with a decrease of $810 as a program change and a decrease of $30,935 as an administrative adjustment.**

In sum, this collection has an annual (non-hour) cost burden of $920,959, with $876,675 in the form of fees, $11,225 in capital start-up costs, $11,700 in recordkeeping costs, and $21,359 in postage costs. **Therefore, this collection has a net decrease in annual (non-hour) cost burden of $3,364,879, with a decrease of $896,920 due to program changes and a decrease of $2,467,959 due to administrative adjustments.**

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.

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.

REFERENCES

A. World Intellectual Property Organization (WIPO) Standard ST.25 (1998)
B. Patent Cooperation Treaty (PCT) Rule 13ter
C. The USPTO Information Quality Guidelines
D. Request for Transfer of a Computer Readable Form under 37 CFR 1.821(e) (PTO/SB/93)