



DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0024 (Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures). The purpose of this notice is to allow 60 days for public comments preceding submission of the information collection to the Office of Management and Budget (OMB).

DATES: To ensure consideration, you must submit comments regarding this information collection on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- Email: InformationCollection@uspto.gov. Include “0651-0024 comment” in the subject line of the message.
- Federal eRulemaking Portal: <http://www.regulations.gov>.

- Mail: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Request for additional information should be directed to Raul Tamayo, Senior Legal Advisor, at: United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; 571-272-7728; or raul.tamayo@uspto.gov with “0651-0024 comment” in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

SUPPLEMENTARY INFORMATION:

I. Abstract

Patent applications that contain nucleotide and/or amino acid sequence disclosures falling within the definitions of 37 CFR 1.831 (for applications filed on or after July 1, 2022) or 37 CFR 1.821(a) (for applications filed on or before June 30, 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 1.831-1.835 or 37 CFR 1.821-1.825, respectively. Applicants may submit sequence listings for both U.S. and international patent applications. For more information concerning the submissions of sequence listings in international applications, see the Patent Cooperation Treaty (PCT) Rules 5.2 and 13^{ter}, Annex C of the PCT Administrative Instructions, and section 1848 of the Manual of Patent Examining Procedure (MPEP) (9th ed., Rev. 01.2024, November 2024).

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. 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.

This information collection only covers the submission of sequence listing information. Information pertaining to the initial filing of a U.S. patent application is collected under OMB

Control Number 0651-0032 (Initial Patent Applications), and information pertaining to the initial filing of international applications is collected under OMB Control Number 0651-0021 (Patent Cooperation Treaty).

For sequence listings filed as 37 CFR 1.825 amendments in applications having a filing date of on or before June 30, 2022, this information collection also accounts for the submission of a new or substitute computer readable form (CRF) copy of the sequence listing under 37 CFR 1.821(e) and 1.824, with the amendment incorporated therein, if necessary, under 37 CFR 1.825(a)(5)(ii) or (b)(6)(ii).

II. Method of Collection

Sequence listings for applications having a filing date of on or after July 1, 2022, must be submitted as XML files, either by electronically transmitting the XML file through the USPTO patent electronic filing system (Patent Center), where the file does not exceed 100MB without compression, or on read-only optical discs. Sequence listings filed as 37 CFR 1.825 amendments in applications having a filing date of on or before June 30, 2022, are preferably submitted as an ASCII plain text file via Patent Center or on a read-only optical disc. They may also be submitted electronically through Patent Center as a PDF or on paper with a submission that is mailed or hand delivered.

III. Data

OMB Control Number: 0651-0024.

Forms: None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 30,000 respondents.

Estimated Number of Annual Responses: 30,000 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 6 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed items to the USPTO.

Estimated Total Annual Respondent Burden Hours: 180,000 hours.

Estimated Total Annual Respondent Hourly Cost Burden: \$80,460,000.

Table 1: Total Burden Hours and Hourly Costs to Private Sector Respondents

Item No.	Item	Estimated Annual Respondents	Responses per Respondent	Estimated Annual Responses	Estimated Time for Response (hours)	Estimated Burden (hour/year)	Rate ¹ (\$/hour)	Estimated Annual Respondent Cost Burden
		(a)	(b)	(a) x (b) = (c)	(d)	(c) x (d) = (e)	(f)	(e) x (f) = (g)
1	Sequence Listing in Application	30,000	1	30,000	6	180,000	\$447	\$80,460,000
	Totals	30,000	---	30,000	---	180,000	---	\$80,460,000

Estimated Total Annual Respondent Non-hourly Cost Burden: \$336,973. There are no capital start-up costs, maintenance costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual non-hour cost burden for this information collection, in the form of filing fees and paid postage, is \$336,973.

Filing Fees

Sequence listings for applications filed on or after July 1, 2022

Applicants must submit sequence listings as XML files, either by electronically transmitting the XML file through Patent Center, where the file does not exceed 100MB without compression, or on read-only optical discs. Accordingly, the size fees for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s), 1.52(f), and 1.492(j), from which XML file submissions via Patent Center or read-only optical discs are excluded, do not apply to sequence listings filed in applications having a filing date of on or after July 1, 2022.

Sequence listings for applications filed on or before June 30, 2022

¹ 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association; pg. F-41. The USPTO uses the average billing rate for intellectual property work in all firms which is \$447 per hour (<https://www.aipla.org/home/news-publications/economic-survey>).

Sequence listings may still be filed in applications having a filing date of on or before June 30, 2022, as amendments that meet the requirements of 37 CFR 1.825. The USPTO prefers that such an amendment be submitted as an ASCII plain text file via Patent Center or a read-only optical disc. If so, the size fees for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s) and 1.52(f), from which ASCII plain text file submissions via Patent Center or read-only optical discs are excluded, do not apply.

However, the USPTO permits the amendment to be submitted electronically through Patent Center as a PDF or on paper. When doing so, the submission may incur a size fee for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s) and 1.52(f).

Specifically, under 37 CFR 1.16(s), if a patent application inclusive of a sequence listing amendment filed as a PDF or on paper exceeds 100 pages, the application size fee is \$450 (\$180 for small entities, \$90 for micro entities) for each additional 50 pages or fraction thereof. For the purposes of this calculation, the USPTO assumes that the average length of a sequence listing filed as a PDF or on paper is 150 pages, which would result in a total size fee of three times the \$450 application size fee under 37 CFR 1.16(s), i.e., \$1,350 (\$540 for small entities, \$270 for micro entities) for applications that are at least 100 pages long prior to the sequence listing amendment. The USPTO estimates that 67 respondents annually will file sequence listing amendments as a PDF or on paper that will require the payment, on average, of \$1,350 for the undiscounted utility application size fee under 37 CFR 1.16(s). The USPTO presents this estimate in Table 2 below as 201 responses annually for the undiscounted utility application size fee under 37 CFR 1.16(s) of \$450 (67 respondents paying the fee three times). Table 2 also reflects similar adjustments for the small and micro entity discounted utility application size fee under 37 CFR 1.16(s).

Mega-sequence listings

Regardless of application filing date, the USPTO's receipt in electronic form of a very lengthy sequence listing (mega-sequence listing) in an application under 35 U.S.C. 111 or 371 is subject to the fee under 37 CFR 1.21(o). In particular, the first receipt by the USPTO of a sequence

listing in electronic form ranging in size from 300MB to 800MB (without file compression) incurs the fee under 37 CFR 1.21(o)(1). The first receipt by the USPTO of a sequence listing in electronic form exceeding 800MB (without file compression) incurs the fee under 37 CFR 1.21(o)(2).

Late furnishing fee in PCT applications

Where a PCT applicant has not provided a sequence listing, and the USPTO acts as the International Searching Authority (ISA) or International Preliminary Examining Authority (IPEA), the USPTO may invite the applicant to furnish a sequence listing, with a late furnishing fee under 37 CFR 1.445(a)(5) and 1.482(c), under PCT Rule 13ter. See section 1848(I) of the MPEP for more information.

Table 2: Filing Fees

Item No.	Fee Code	Item	Estimated Annual Respondents Paying a Fee (a)	Number of Responses Per Respondent (b)	Estimated Annual Number of Fees Being Paid (c)	Filing Fee (\$) (d)	Non-hourly Cost Burden (c) x (d) = (e)
1	1081	Utility application size fee under 37 CFR 1.16(s) (undiscounted entity)	67	3	201	\$450	\$90,450
1	2081	Utility application size fee under 37 CFR 1.16(s) (small entity)	82	3	246	\$180	\$44,280
1	3081	Utility application size fee under 37 CFR 1.16(s) (micro entity)	1	3	3	\$90	\$270
1	1091	Submission of sequence listings of 300MB to 800MB (undiscounted entity)	10	1	10	\$1,140	\$11,400
1	2091	Submission of sequence listings of 300MB to 800MB (small entity)	1	1	1	\$456	\$456
1	3091	Submission of sequence listings of 300MB to 800MB (micro entity)	1	1	1	\$228	\$228
1	1092	Submission of sequence listings of more than 800MB (undiscounted entity)	1	1	1	\$11,290	\$11,290
1	2092	Submission of sequence listings of more than 800MB (small entity)	1	1	1	\$4,516	\$4,516
1	3092	Submission of sequence listings of more than 800MB (micro entity)	1	1	1	\$2,258	\$2,258

Item No.	Fee Code	Item	Estimated Annual Respondents Paying a Fee (a)	Number of Responses Per Respondent (b)	Estimated Annual Number of Fees Being Paid (c)	Filing Fee (\$) (d)	Non-hourly Cost Burden (c) x (d) = (e)
1	1627	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13 ^{ter} (undiscounted entity)	230	1	230	\$345	\$79,350
1	2627	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13 ^{ter} (small entity)	645	1	645	\$138	\$89,010
1	3627	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13 ^{ter} (micro entity)	5	1	5	\$69	\$345
		Totals	1,045	---	1,345	---	\$333,853

Postage Costs

Sequence listings filed as 37 CFR 1.825 amendments in applications having a filing date of on or before June 30, 2022, may be submitted by mail through the United States Postal Service. The USPTO estimates that at most 1% of the 30,000 items will be submitted in the mail resulting in 300 mailed items. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail legal flat rate envelope, will be \$10.40. Therefore, the USPTO estimates the total mailing costs for this information collection at \$3,120.

IV. Request for Comments

The USPTO is soliciting public comments to:

- (a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. The USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While one may ask in a comment to withhold PII from public view, the USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2025-11798 Filed: 6/25/2025 8:45 am; Publication Date: 6/26/2025]