SUPPORTING STATEMENT
United States Patent and Trademark Office
Patent Term Extension and Adjustment
OMB CONTROL NUMBER 0651-0020
2023

A. JUSTIFICATION

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

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417), which is codified at 35 U.S.C. 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or United States Department of Agriculture (USDA). Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. 156 is 5 years. The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710–1.791.

This information collection covers information gathered in patent term extension applications submitted under 35 U.S.C. 156(d). Under this provision, an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product, or a method of manufacturing the approved product. 35 U.S.C. 156(d) also requires the submission of information that enables the USPTO to determine the eligibility of the patent for extension, and the rights that will be derived from the extension, and information to enable the USPTO and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension. Additionally, 35 U.S.C. 156(d) requires the applicant for patent term extension to provide a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities.

This information collection also covers information gathered in requests for interim extensions pursuant to 35 U.S.C. 156(d)(5) and 156(e)(2). Under 35 U.S.C. 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect. Under 35 U.S.C. 156(e)(2), an interim extension may be granted if

the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. In addition, this information collection covers requests for review of final eligibility decisions, and requests to withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases adjust the term of an original patent under the provisions of 35 U.S.C. 154 due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse USPTO determination of patentability. The USPTO administers 35 U.S.C. 154 through 37 CFR 1.701–1.705. The patent term provisions of 35 U.S.C. 154(b), as amended by Title IV, Subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, allow the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination. This information collection covers information gathered in such a request. In addition, this information collection covers information collected when the USPTO reduces the amount of a granted patent term adjustment if delays were caused by an applicant's failure to make a reasonable effort to respond to a communication from the USPTO within three months of the communication's mailing date. Applicants may petition for reinstatement of a reduction in patent term adjustment with a showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period.

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

Table 1: Information Requirements

Item No.	Requirement	Statute	Regulation
1	Application to Extend Patent Term Under 35 U.S.C. 156	35 U.S.C. 156(d)(1)-(4)	37 CFR 1.740-1.741
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	35 U.S.C. 156(e)(2)	37 CFR 1.760
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	35 U.S.C. 156(d)	37 CFR 1.750
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	35 U.S.C. 156(d)(5)	37 CFR 1.790
5	Subsequent Application for Interim Extension Under 35 CFR 1.790	35 U.S.C. 156(d)(5)	37 CFR 1.790
6	Response to Requirement to Elect a Single Patent to Extend from a Single Regulatory Review Period	35 U.S.C. 156(c)(4)	37 CFR 1.785(b)

7	Response to Request to Identify Holder of Regulatory Approval	35 U.S.C. 156(d)(1)(E)	37 CFR 1.785(d)
8	Declaration to Withdraw an Application to Extend Patent Term	35 U.S.C. 156	37 CFR 1.770
9	Petition for Reconsideration of Patent Term Adjustment Determination	35 U.S.C. 154(b)(3)(B)(ii)	37 CFR 1.705
10	Petition for Reinstatement of Reduced Patent Term Adjustment	35 U.S.C. 154(b)(3)(C)	37 CFR 1.705
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	35 U.S.C. 156(d)(1)-(4)	37 CFR 1.741(b)

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

The public uses this information collection to file: patent term extension applications, including interim applications under 35 U.S.C. 156(d)(5); follow-on documentation related to the extension applications, including requests for interim extensions under 35 U.S.C. 156(e)(2); and reconsideration or reinstatement of patent term adjustments granted under 35 U.S.C. 154. The information in this information collection is used by the USPTO to consider whether an applicant is eligible for a patent term extension or reconsideration of a patent term adjustment and, if so, to determine the length of the patent term extension or adjustment.

The information collected, maintained, and used in this information 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 information is used by the public and the USPTO:

Table 2: Needs and Uses

Item No.	Form and Function	Form No.	Needs and Uses
1	Application to Extend Patent Term Under 35 U.S.C. 156	No Form Associated	• Used by the public to apply for a patent term extension. • Used by the USPTO and the United States Department of Health and Human Services or the United States Department of Agriculture to determine eligibility of a patent for extension and to determine the period of extension.
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	No Form Associated	• Used by the public to request an interim extension. • Used by the USPTO to trigger an interim extension before processing of the patent term extension application has been completed.
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	No Form Associated	• Used by the public to petition the USPTO to review final patent term extension eligibility decisions. • Used by the USPTO to review final patent term extension eligibility decisions, as long as the petition is filed within a set time.

Item No.	Form and Function	Form No.	Needs and Uses
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	No Form Associated	• Used by the public to apply for an interim extension. • Used by the USPTO to determine eligibility of a patent for interim extension.
5	Subsequent Application for Interim Extension Under 35 CFR 1.790	No Form Associated	• Used by the public to apply for a subsequent interim extension. • Used by the USPTO to determine eligibility of a patent for subsequent interim extension.
6	Response to Requirement to Elect a Single Patent to Extend from a Single Regulatory Review Period	No Form Associated	• Used by the public to elect which patent to extend when more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period. • Used by the USPTO to determine which patent of more than one patent to extend, or which regulatory review period of more than one regulatory review period to use in the determination of the length of patent term extension.
7	Response to Request to Identify Holder of Regulatory Approval	No Form Associated	• Used by the public identify the holder of the regulatory approval granted with respect to the regulatory review period pertaining to the application for extension. • Used by the USPTO to determine eligibility of patent owner to obtain an extension of a patent.
8	Declaration to Withdraw an Application to Extend Patent Term	No Form Associated	• Used by the public to withdraw an application to extend a patent term. • Used by the USPTO to avoid extending patents that the patent owner no longer seeks to extend.
9	Petition for Reconsideration of Patent Term Adjustment Determination	No Form Associated	• Used by the patentee to request reconsideration of the USPTO's patent term adjustment determination. • Used by the USPTO to determine whether its patent term adjustment determination is in error. • Used by the USPTO to determine the correct patent term adjustment.
10	Petition for Reinstatement of Reduced Patent Term Adjustment	No Form Associated	• Used by the patentee to request reinstatement of reduced patent term adjustment. • Used by the USPTO to determine whether the patentee is entitled to reinstatement of reduced patent term adjustment.
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	No Form Associated	• Used by the patentee to request review of a notice of an incomplete application for extension of a patent term and to request a filing date. • Used by the USPTO to determine the filing date for an application for extension of a patent term.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological information 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 information collection. Also describe any consideration of using information technology to reduce burden.

Except for the Application to Extend Patent Term Under 35 U.S.C. 156 and the Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5), customers may submit the items in this information collection electronically through the USPTO patent electronic filing system (EFS-Web and Patent Center), the USPTO's online filing systems for

patent applications and related documents. The USPTO patent electronic filing system allows customers to file requests related to patent term extensions and adjustments through their standard Web browser without downloading special software, changing their documentation preparation tools, or altering their workflow processes. Customers may create their requests using the tools and processes that they already use and then convert those documents into standard PDF files that are submitted through the USPTO patent electronic filing system to the USPTO.

Registered and unregistered users can file documents through the USPTO patent electronic filing system. The documents are submitted to the USPTO patent electronic filing system using Transport Layer Security (TLS) or Secure Socket Layer (SSL) protocol.

The USPTO patent electronic filing system offers many benefits to filers, including immediate notification that a submission has been received by the USPTO, automated processing of requests, and avoidance of postage and other paper delivery costs. Users can access the USPTO patent electronic filing system from any computer with an Internet connection. Since the USPTO patent electronic filing system is hosted on the USPTO's secure servers and not on the individual's personal computer, USPTO staff can update the USPTO patent electronic filing system without requiring any action from the user. Customers can submit fee payments and other requests in real time. The PDF forms can be passed around to multiple users for collaboration.

The USPTO patent electronic filing system permits only authorized individuals to access information about pending patent applications and maintains the confidentiality and integrity of the information as it is transmitted over the Internet. Information for issued patents, including patent term adjustments, is available to the general public. The USPTO also publishes determinations on applications for patent term extensions directly on the USPTO Web site.

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 information is collected only when an applicant submits a request related to a patent term extension or patent term adjustment. Requests for patent term extensions can only be filed with the USPTO. The information needed by the USPTO, the FDA, the USDA, or other federal government agencies to consider such requests is not already available from any other source. This information is not collected elsewhere and does not result in a duplication of effort.

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

The USPTO does not expect that this information collection will have a significant economic impact on a substantial number of small businesses or other small entities. Patent term extensions under 35 U.S.C. 156 are only for patents for drug products, medical devices, food or color additives, or methods of using or manufacturing such products, devices, or additives. Patent term extensions are typically requested by large pharmaceutical companies because of the expense required to develop and obtain marketing approval for such inventions. USPTO estimates that 25% of these responses are submitted by small entities. The same information is required from every respondent, and this information is not available from any other source.

Pursuant to section 10(b) of the Leahy-Smith America Invents Act (AIA), the USPTO provides a 50% reduction in the fees for certain patent filings by small entity applicants, such as independent inventors, small businesses, and nonprofit organizations who meet the definition of a small entity provided at 37 CFR 1.27. Also pursuant to section 10(b) of the AIA, the USPTO provides a 75% reduction in the fees set or adjusted under section 10(a) of the Act for certain patent filings by applicants who meet the definition of a micro entity provided at 35 U.S.C. 123 and 37 CFR 1.29.

The reduced patent fees for small and micro entity filers of the Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term are listed at 37 CFR 1.17(f). No significant burden is placed on small or micro entities, in that small entities must only identify themselves as such in order to obtain these benefits, and micro entities must only provide a certification of micro entity status. An assertion or certification of small or micro entity status, respectively, only needs to be filed once in an application or patent (although a fee may be paid in the micro entity amount only if the applicant or patentee is still entitled to micro entity status on the date the fee is paid).

6. Describe the consequence to Federal program or policy activities if the information collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The information for a patent term or interim extension is collected only when the applicant files an application with the USPTO. This information could not be collected less frequently. If the information were not collected as provided in 35 U.S.C. 156(d)(1) or (d)(5), the Director of the USPTO, the Secretary of Health and Human Services, and the Secretary of Agriculture would not have access to the information required to determine whether the applicant is eligible for a patent term extension and, if so, the period of the extension.

There is no requirement that any patent owner apply for an extension. However, if a request for an extension is made, sufficient information is required by the agencies to determine whether the statutory requirements for the special benefit have been met. There is no set frequency of periodic intervals in which the information requested must

be supplied. The submission of a request for a patent term extension is at the discretion of the patent owner and is normally limited to one submission within 60 days of approval of a product for commercial use or sale by the FDA or the USDA.

The information for the petitions for reconsideration of patent term adjustment determination and for reinstatement of reduced patent term adjustment is collected only as requested and is not found elsewhere. If the information were not collected, the USPTO would not be able to comply with the statute and regulations that permit applicants to request reconsideration of a patent term adjustment determination.

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 information 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.

A 60-Day Notice was published in the *Federal Register* on November 21, 2022 (87 FR 70788).[1] The comment period ended on January 20, 2023. No public comments were received.

The USPTO has long-standing relationships with groups from whom patent application information is collected, such as the American Intellectual Property Law Association, as well as 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 information 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). 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.

Applications filed through the USPTO patent electronic filing system are maintained in confidence as required by 35 U.S.C.122(a) until the application is published or a patent

1 https://www.govinfo.gov/content/pkg/FR-2022-11-21/pdf/2022-25314.pdf.

is issued. The confidentiality, security, integrity, authenticity, and non-repudiation of patent applications submitted electronically through the USPTO patent electronic filing system are maintained using PKI technology and digital certificates for registered users. Applications electronically-filed by non-registered users are protected using TLS or SSL protocols. The USPTO posts issued patents and application publications on its Web site. The information covered under this information collection will not be released to the public unless it is part of an issued patent or application publication. Patent applicants and/or their designated representatives can view the current status of their patent application through the Private PAIR system. Patent term extensions involve issued patents and therefore typically do not have confidentiality issues, but there may be confidentiality considerations for patent term adjustments.

The Privacy Act of 1974 (P.L. 93-579) requires that an applicant be given certain information in connection with submissions related to a patent application or issued patent. The USPTO collects information under authority of 35 U.S.C. 2. The purpose of the USPTO's system of records is to carry out the duties of the USPTO to examine patent applications and issue patents, including the collection of the inventor's oath or declaration under 35 U.S.C. 115. 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 or has been granted.

The information, in this system of records, is protected from disclosure to third parties in accordance with the Privacy Act. However, routine uses of this information may include publication under 35 U.S.C. 112(a) as noted above, and disclosure to the following: to law enforcement 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 (FOIA) assistance; to a Member of Congress working on behalf of an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record; to the Office of Personnel Management (OPM) for personnel research purposes; to National Archives and Records Administration for inspection of records; and to the Office of Management and Budget (OMB) for legislative coordination and clearance. failure to provide any part of the requested information may result in an inability to process requests related to patent applications or issued 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 applicable Privacy Act System of Records Notice for this information is COMMERCE/PAT-TM-7 Patent Application Files, available at the Federal Register at 78 FR 19243 (March 29, 2013).[2]

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 information 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'.**

Table 2 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 915 responses per year for this information collection, with approximately 25% of these respondents

2 https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf.

submitted by small entities. Approximately 99% of the total responses for this information collection will be submitted electronically.

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

- **Burden Hour Calculation Factors**
  The USPTO estimates that it will take the public from 1 to 25 hours, depending on the complexity and type of filing, to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

  These estimates are based on the Agency's long-standing institutional knowledge of and experience with the type of information collected and the length of time necessary to complete responses containing similar or like information. Using these burden factors, USPTO estimates that the total respondent hourly burden for this information collection is 6,113 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). The USPTO expects that the information in this information collection will be prepared for by attorneys. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this information collection is $2,659,155 per year.

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

Item No.	Item Name	Estimated Annual Respondents (a)	Respondents per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hour) (d)	Total Annual Hour Burden (c) x (d) = (e)	Hourly Cost Burden Rate[3] (f)	Total Annual Cost for Time Spent (e) x (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156	146	1	146	25	3,650	$435	$1,587,750
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	29	1	29	1	29	$435	$12,615
3	Petition to review final Eligibility Decision Under 37 CFR 1.750	2	1	2	25	50	$435	$21,750

3 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg. F-27. The USPTO uses the average billing rate for intellectual property attorneys in private firms which is $435 per hour.

4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	8	1	8	20	160	$435	$69,600
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	7	1	7	1	7	$435	$3,045
6	Response to Requirement to Elect a Single Patent to Extend from a Single Regulatory Review Period	39	1	39	1	39	$435	$16,965
7	Response to Request to Identify Holder of Regulatory Approval	2	1	2	2	4	$435	$1,740
8	Declaration to Withdraw an Application to Extend Patent Term	1	1	1	2	2	$435	$870
9	Petition for Reconsideration of Patent Term Adjustment Determination	631	1	631	3	1,893	$435	$823,455
10	Petition for Reinstatement of Reduced Patent Term Adjustment	14	1	14	4	56	$435	$24,360
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	4	1	4	2	8	$435	$3,480
	Totals	**883**	**- - -**	**883**	**- - -**	**5,898**	**- - -**	**$2,565,630**

Table 4: Burden Hours and Hourly Costs to Individual and Household Respondents

Item No.	Item Name	Estimated Annual Respondents (a)	Respondents per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hour) (d)	Total Annual Hour Burden (c) x (d) = (e)	Hourly Cost Burden Rate[4] (f)	Total Annual Cost for Time Spent (e) x (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156	4	1	4	25	100	$435	$43,500

4 Ibid.

2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	1	1	1	1	1	$435	$435
3	Petition to review final Eligibility Decision Under 37 CFR 1.750	1	1	1	25	25	$435	$10,875
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	1	1	1	20	20	$435	$8,700
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	1	1	$435	$435
6	Response to Requirement to Elect	1	1	1	1	1	$435	$435
7	Response to Request to Identify Holder of Regulatory Approval	1	1	1	2	2	$435	$870
8	Declaration to Withdraw an Application to Extend Patent Term	1	1	1	2	2	$435	$870
9	Petition for Reconsideration of Patent Term Adjustment Determination	19	1	19	3	57	$435	$24,795
10	Petition for Reinstatement of Reduced Patent Term Adjustment	1	1	1	4	4	$435	$1,740
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	1	1	1	2	2	$435	$870
	Totals	**32**	**- - -**	**32**	**- - -**	**215**	**- - -**	**$93,525**

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 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.**
- **Generally, estimates should not include purchases of equipment or services, or portions therefor, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

There are no maintenance costs, capital start-up 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 postage, is $327,003.

Fees

The fees associated with the requirements in this information collection are listed in the table below.

Table 5: Filing Fees and Non-Hour Costs to Respondents

Item No.	Item	Annual Estimated Responses	Filing Fee	Total Cost
1	Application to Extend Patent Term Under 35 U.S.C. 156	150	$1,180	$177,000
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	10	$440	$4,400
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	10	$230	$2,300
9	Petition for Reconsideration of Patent Term Adjustment Determination	650	$210	$136,500
10	Petition for Reinstatement of Reduced Patent Term Adjustment	15	$420	$6,300
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	1	$420	$420
	Totals	**836**	**- - -**	**$326,920**

Therefore, the total non-hourly cost in the forms of filing fees amounts to this information collection is $326,920.

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 expects that approximately 1% of the 915 responses in this information collection will be submitted in the mail, resulting in 9 mailed submissions. 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. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this information collection will total $83.

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of filing fees ($326,920) and postage costs ($83) is $327,003 per year.

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 costs estimates from Items 12, 13, and 14 in a single table.

The USPTO estimates that it takes USPTO staff approximately 15 minutes (0.25 hours) to 2 hours to process the information in this information collection, depending on the type and amount of information submitted. The USPTO estimates that the cost of a GS-5, step 1 employee is $25.47 per hour (GS hourly rate of $19.59 with 30% ($5.88) added for benefits and overhead). The USPTO estimates that it takes an employee between 15 minutes (0.25 hours) and 2 hours to process the information in this information collection. The overall costs to the Federal Government for processing this information is $25,139.

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

Table 6: Burden Hour/Cost to the Federal Government

Item No.	Item	Responses (yr) (a)	Hours (b)	Burden (hrs/yr) (c) (a x b)	Rate[5] ($/yr) (d)	Total Cost ($/yr) (e) (d x e)

5 https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB_h.pdf.

1	Application to Extend Patent Term Under 35 U.S.C. 156	150	2	300	$25.47	$7,641
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	30	0.50	15	$25.47	$382
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	3	0.25	1	$25.47	$25
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	9	0.50	5	$25.47	$127
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	8	0.50	4	$25.47	$102
6	Response to Requirement to Elect	40	0.25	10	$25.47	$255
7	Response to Request to Identify Holder of Regulatory Approval	3	0.25	1	$25.47	$25
8	Declaration to Withdraw an Application to Extend Patent Term	2	0.25	1	$25.47	$25
9	Petition for Reconsideration of Patent Term Adjustment Determination	650	1	650	$25.47	$16,556
10	Petition for Reinstatement of Reduced Patent Term Adjustment	15	1	15	$25.47	$397
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	5	0.25	1	$25.47	$27
	Totals	**915**	**- - -**	**1,003**	**- - -**	**0**

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	915	0	0	295	0	620
Annual Time Burden (Hr)	6,113	0	0	2,011	0	4,102
Annual Cost Burden ($)	327,003	0	0	117,114	0	209,889

Estimated Annual Responses and Hourly Burdens due to Adjustment in Agency Estimate

The increase in the number of responses (+295) and burden hours (+2,011) is due to the estimated normal fluctuation in the number of responses for the items in this

information collection.

Change in Annual (Non-hour) Costs due to Adjustment in Agency Estimate

The USPTO estimates an increase (+$117,114) for the total annual (non-hour) costs due to the increase in the number of respondents paying filing fees and postage. Likewise, USPTO increased its estimates for postage costs to reflect more accurate respondent burden.

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 or for any special purpose. However, plant and utility patents granted are included weekly in the *Official Gazette of the United States Patent and Trademark Office for Patents* (Official Gazette for Patents), which is published in electronic format on the USPTO Web site.[6] The USPTO also publishes determinations on applications for patent term extension on the USPTO Web site as required by the Freedom of Information Act and lists any certificates of extension granted in the *Official Gazette for Patents*.

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 expiration date for 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. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.

6 https://www.uspto.gov/learning-and-resources/official-gazette/official-gazette-patents.