

SUPPORTING STATEMENT
United States Patent and Trademark Office
Patent Term Extension
OMB CONTROL NUMBER 0651-0020
(October 2016)

A. JUSTIFICATION

1. Necessity of Information Collection

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (P.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 Department of Agriculture. 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 five years.

Under 35 U.S.C. § 156(d), 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 application 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.

Under 35 U.S.C. § 156(e), 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. 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.

The USPTO administers 35 U.S.C. § 156 through 37 CFR 1.710-1.791. These rules provide for the public to, *inter alia*, submit 35 U.S.C. § 156 patent term extension applications to the USPTO, request interim extensions and review of final eligibility decisions, and 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 extend the term of an original patent 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 determination of

patentability. 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, require the USPTO to notify the applicant of the patent term adjustment in the notice of allowance and give the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination.

The USPTO may also reduce the amount of patent term adjustment granted if delays were caused by an applicant's failure to make a reasonable effort to respond within three months of the mailing date of a communication from the USPTO. 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. The USPTO administers 35 U.S.C. § 154 through 37 CFR 1.701-1.705.

2. Needs and Uses

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. The information in this 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 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 1 lists the specific statutes and regulations authorizing the USPTO to collect this information and outlines how this information is used by the public and the USPTO:

Table 1: Information Requirements and Needs and Uses of Information Collected

Item #	Requirement	Statute	Rule	Form #	Needs and Uses
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	No Form Associated	<ul style="list-style-type: none"> Used by the public to apply for a patent term extension. Used by the USPTO and the Department of Health and Human Services or the 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)	35 U.S.C. § 156(e)(2)	37 CFR 1.760	No Form Associated	<ul style="list-style-type: none"> Used by the public to request an interim extension. Used by the USPTO to trigger an interim extension before processing of the application has been completed.

Item #	Requirement	Statute	Rule	Form #	Needs and Uses
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	35 U.S.C. § 156(d)	37 CFR 1.750	No Form Associated	<ul style="list-style-type: none"> Used by the public to petition the USPTO to review final eligibility decisions. Used by the USPTO to review final eligibility decisions, as long as the petition is filed within a set time.
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	No Form Associated	<ul style="list-style-type: none"> 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	35 U.S.C. § 156(d)(5)	37 CFR 1.790	No Form Associated	<ul style="list-style-type: none"> 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	35 U.S.C. § 156(c)(4)	37 CFR 1.785(b)	No Form Associated	<ul style="list-style-type: none"> Used by the public to elect which patent of more than one patent to extend. 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	35 U.S.C. § 156(d)(1)(E)	37 CFR 1.785(d)	No Form Associated	<ul style="list-style-type: none"> Used by the public to declare eligibility to apply for a patent term 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	35 U.S.C. § 156	37 CFR 1.770	No Form Associated	<ul style="list-style-type: none"> 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	35 U.S.C. § 154(b)(3)(B)(ii)	37 CFR 1.705	No Form Associated	<ul style="list-style-type: none"> Used by the patentee to correct errors in 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	35 U.S.C. § 154(b)(3)(C)	37 CFR 1.705	No Form Associated	<ul style="list-style-type: none"> 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	35 U.S.C. § 156(d)(1)-(4)	37 CFR 1.741(b)	No Form Associated	<ul style="list-style-type: none"> 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. Use of Information Technology

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 EFS-Web, the USPTO's online filing system for patent applications and related documents. EFS-Web 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 EFS-Web to the USPTO.

Registered and unregistered users can file documents through EFS-Web. The documents of registered users are protected using a Public Key Infrastructure (PKI) system and digital certificates which provide authentication and encryption security. For filers who are not registered, the documents are submitted to EFS-Web using Transport Layer Security (TLS) or Secure Socket Layer (SSL) protocol.

EFS-Web 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 EFS-Web from any computer with an Internet connection. Since EFS-Web is hosted on the USPTO's secure servers and not on the individual's personal computer, USPTO staff can update EFS-Web 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.

EFS-Web integrates with the Patent Application Information Retrieval (PAIR) system, the USPTO's online database that is available through the USPTO Web site. PAIR uses digital certificates to permit only authorized individuals to access information about pending patent applications and to maintain 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. Efforts to Identify Duplication

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 Department of Health and Human Resources, the Department of Agriculture, 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. Minimizing Burden to Small Entities

The USPTO does not expect that this 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. 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. Consequences of Less Frequent Collection

The information for a patent term or interim extension is collected only when the applicant files an application with the USPTO and 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 Food and Drug Administration or the Department of Agriculture.

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. Special Circumstances in the Conduct of Information Collection

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

8. Consultations Outside the Agency

A 60-Day Notice was published in the *Federal Register* on August 22, 2016 (81 Fed. Reg. 56608). The comment period ended on October 21, 2016. No public comments were received.

9. Payment or Gifts to Respondents

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

10. Assurance of Confidentiality

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. Patent term extensions involve issued patents and therefore typically do not have confidentiality issues, but there may be confidentiality considerations for patent term adjustments.

11. Justification for Sensitive Questions

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

12. Estimate of Hour and Cost Burden to Respondents

Table 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 1,340 responses per year for this collection, with approximately 25% of these responses submitted by small entities. Approximately 93% of the total responses for this collection will be submitted electronically.

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

- ### Burden Hour Calculation Factors

The USPTO estimates that it will take the public 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.

- ### Cost Burden Calculation Factors

The USPTO uses a professional rate of \$410 per hour for respondent cost burden calculations, which is the mean rate for attorneys in private firms as shown in the 2015 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA).

Table 2: Burden Hour/Burden Cost to Respondents

Item #	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a x b)	Rate (\$/yr) (d)	Total Cost (\$/yr) (e) (d x e)
1	Application to Extend Patent Term Under 35 U.S.C. § 156	25	95	2,375	\$410.00	\$973,750.00
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	1	10	10	\$410.00	\$4,100.00
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	25	4	100	\$410.00	\$41,000.00
4	Initial Application for Interim Extension Under 37 CFR 1.790	20	2	40	\$410.00	\$16,400.00

Item #	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a x b)	Rate (\$/yr) (d)	Total Cost (\$/yr) (e) (d x e)
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	\$410.00	\$410.00
6	Response to Requirement to Elect	1	15	15	\$410.00	\$6,150.00
7	Response to Request to Identify Holder of Regulatory Approval	2	1	2	\$410.00	\$820.00
8	Declaration to Withdraw an Application to Extend Patent Term	2	1	2	\$410.00	\$820.00
9	Petition for Reconsideration of Patent Term Adjustment Determination	3	1,200	3,600	\$410.00	\$1,476,000.00
10	Petition for Reinstatement of Reduced Patent Term Adjustment	4	10	40	\$410.00	\$16,400.00
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	2	1	2	\$410.00	\$820.00
	Totals	---	1,340	6,187	---	\$2,536,670.00

13. Total Annual (Non-hour) Cost Burden

This total annual (non-hour) cost burden for this collection is calculated in Table 3 below. Postage and filing fees are included in this ICR. This collection has no capital start-up, maintenance, or recordkeeping costs.

Postage

The USPTO expects that approximately 93 percent of the responses in this collection will be submitted electronically. Of the remaining 7 percent, the vast majority—98 percent—will be submitted by mail, for a total of 92 mailed submissions. The average first class USPS postage cost for a mailed submission is 49 cents. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this collection will total \$45.08.

Fees

There are fees associated with the requirements in this collection. In the previous renewal they had been moved to collection 0651-0072, but have since been returned for more accurate reporting. The fees associated with this collection are listed below.

Table 3: Fees

Item #	Item	Responses	Filing Fee	Cost
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1	Filing an application for patent term adjustment	1,200	\$200.00	\$240,000.00
2	Request for reinstatement of term reduced	10	\$400.00	\$4,000.00
3	Extension of term of patent	95	\$1,120.00	\$106,400.00
4	Initial application for interim extension (see 37 CFR 1.790)	2	\$420.00	\$420.00
5	Subsequent application for interim extension (see 37 CFR 1.790)	1	\$220.00	\$220.00
	Totals	1,340		\$351,460.00

Therefore, the total non-hourly cost in the forms of filing fees and postage amounts to \$351,505.08.

14. Annual Cost to the Federal Government

The USPTO estimates that it takes a GS-5, step 1 employee between 15 minutes (0.25 hours) and 2 hours to process the information in this collection at an estimated cost of \$21.97 per hour (GS-5/1 hourly rate of \$16.90 with 30% (\$5.07) added for benefits and overhead). Table 4 calculates the burden hours and costs to the Federal Government for processing this information collection:

Table 4: Burden Hour/Cost to the Federal Government

Item #	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a x b)	Rate (\$/yr) (d)	Total Cost (\$/yr) (e) (d x e)
1	Application to Extend Patent Term Under 35 U.S.C. § 156	2.00	95	190	\$21.97	\$4,174.30
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	0.50	10	5	\$21.97	\$109.85
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	0.25	4	1	\$21.97	\$21.97
4	Initial Application for Interim Extension Under 35 U.S.C. § 156(d)(5)	0.50	2	1	\$21.97	\$21.97
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	0.50	1	0.5	\$21.97	\$10.99
6	Response to Requirement to Elect	0.25	15	3.75	\$21.97	\$82.39
7	Response to Request to Identify Holder of Regulatory Approval	0.25	1	0.25	\$21.97	\$5.49
8	Declaration to Withdraw an Application to Extend Patent Term	0.25	1	0.25	\$21.97	\$5.49
9	Petition for Reconsideration of Patent Term	1.00	1,200	1,200	\$21.97	\$26,364.00

	Adjustment Determination					
10	Petition for Reinstatement of Reduced Patent Term Adjustment	1.00	10	10	\$21.97	\$219.70
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	0.25	1	0.25	\$21.97	\$5.49
	Totals	- - - -	0	0	- - - -	0

15. Reasons for Changes in Burden

Summary of Changes Since the Previous Renewal

OMB previously approved this information collection in October of 2013 with 1,950 responses, 7,252 burden hours, and \$90.00 in annual (non-hour) costs. For this proposed renewal, the USPTO estimates that the total annual responses will be 1,340 and the total annual burden hours will be 6,187. This decrease of 610 responses and 1,065 burden hours is due to administrative adjustments.

The currently approved annual (non-hour) cost burden for this collection is \$90.00. For this renewal, the USPTO estimates that the total annual (non-hour) costs will be \$351,505.08. This increase of \$351,415.08 is due to the return of filing fees from collection 0651-0072.

Changes in Respondent Cost Burden

The total respondent cost burden for this collection has decreased by \$153,822.00, from \$2,690,492.00 to \$2,536,670.00, from the previous renewal of this collection in October of 2013, which is due to administrative adjustments. This decrease will occur in spite of the increase in the attorney rate used by the USPTO.

Changes in Responses and Burden Hours

For this renewal, the USPTO estimates that the total annual responses will increase by 299 (from 10,766 to 11,065) and the total burden hours will decrease by 1,065 (from 7,252 to 6,187) from the currently approved burden for this collection. These changes are due to the following administrative adjustments:

- **Decrease of 610 estimated annual responses.** The USPTO estimates that this collection will receive 610 fewer annual responses annually over the three-year period covered by this renewal request. This adjustment caused the number of burden hours for this item to fall by 1,065.

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

The total annual (non-hour) cost burden for this renewal submission of \$351,505.08 is an increase of \$351,415.08 from the currently approved total of \$90.00. This increase is due to the return of the filing fees that were previously located in collection 0651-0072.

Administrative adjustments

- Postage: Increase in part due to adjustments in the estimated number of mailed submissions as well as a small increase in USPS first-class postage rates since the previous renewal.

Changes in Federal Government Cost Burden

For this renewal submission, the USPTO estimates that the federal government cost burden for processing the items in this collection will decrease by \$11,268.36, from \$42,290.00 to \$31,021.64, due to an administrative adjustment, as follows:

- **Decrease in respondents.** Despite an increase in the Federal wage rates, the overall number of respondents decreased by 610 from the previous renewal.

16. Project Schedule

The USPTO does not plan to publish this information for statistical use or for any special purpose. However, plant and utility patents granted are published 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. 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. Display of Expiration Date of OMB Approval

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

18. Exceptions 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.