

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

A. JUSTIFICATION

1. Necessity of Information Collection

The Federal Food, Drug and Cosmetic Act at 35 U.S.C. § 156 permits the United States Patent and Trademark Office (USPTO) to restore the patent term lost due to certain types of regulatory review by the Federal Food and Drug Administration or the Department of Agriculture. Only patents for drug products, medical devices, food additives, and color additives are eligible for extension. The maximum length that a patent may be extended in order to restore the lost portion of the patent term is five years.

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 Board of Patent Appeals and Interferences 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 and § 156 through 37 CFR 1.701-1.791. These rules permit the public to submit applications to the USPTO to extend the term of a patent past its original expiration date, to request interim extensions and review of final eligibility decisions, and to withdraw an application requesting a patent term extension after it is submitted. Under 35 U.S.C. § 156(d), an application for patent term extension must identify the approved product, the patent to be extended, the claims included in the patent for the approved product, and a method of use or manufacturing for the approved product. In addition, the application for patent term extension must 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.

The term of a patent that claims a product, a method of using a product, or a method of manufacturing a product shall be extended if the term of the patent has not expired before an application is submitted. The Federal Food, Drug and Cosmetic Act requires that an application for patent term extension be filed with the USPTO within 60 days of the product receiving regulatory approval from the Federal Food and Drug Administration or the Department of Agriculture. 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 under 35 U.S.C. § 156(d) would expire before a certificate of extension is issued.

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

Table 1: Information Requirements for Patent Term Extensions and Adjustments

Requirement	Statute	Rule
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
Request for Interim Extension under 35 U.S.C. § 156(e)(2)	35 U.S.C. § 156(e)(2)	37 CFR 1.760
Petition to Review Final Eligibility Decision under 37 CFR 1.750	35 U.S.C. § 156(d)	37 CFR 1.750
Initial Application for Interim Extension under 35 U.S.C. § 156(d)(5)	35 U.S.C. § 156(d)(5)	37 CFR 1.790
Subsequent Application for Interim Extension under 37 CFR 1.790	35 U.S.C. § 156(d)(5)	37 CFR 1.790
Response to Requirement to Elect	35 U.S.C. § 156(c)(4)	37 CFR 1.785(b)
Response to Request to Identify Holder of Regulatory Approval	35 U.S.C. § 156(d)(1)(E)	37 CFR 1.785(d)
Declaration to Withdraw an Application to Extend Patent Term	35 U.S.C. § 156	37 CFR 1.770
Petition for Reconsideration of Patent Term Adjustment Determination	35 U.S.C. § 154(b)(3)(B)(ii)	37 CFR 1.705
Petition for Reinstatement of Reduced Patent Term Adjustment	35 U.S.C. § 154(b)(3)(C)	37 CFR 1.705
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. Needs and Uses

The public uses this information collection to file requests related to patent term extensions and petitions for 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. There are no forms associated with this collection.

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 Patent Term Extensions and Adjustments

Form and Function	Form #	Needs and Uses
Application to Extend Patent Term under 35 U.S.C. § 156	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.
Request for Interim Extension under 35 U.S.C. § 156(e)(2)	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.
Petition to Review Final Eligibility Decision under 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.
Initial Application for Interim Extension under 35 U.S.C. § 156(d)(5)	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.
Subsequent Application for Interim Extension under 35 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.
Response to Requirement to Elect	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.
Response to Request to Identify Holder of Regulatory Approval	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.
Declaration to Withdraw an Application to Extend Patent Term	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.

Petition for Reconsideration of Patent Term Adjustment Determination	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.
Petition for Reinstatement of Reduced Patent Term Adjustment	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.
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	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

Currently, the USPTO does not use automated, electronic, mechanical, or other technologies to collect the information for this collection. Customers may submit the information in this collection to the USPTO by mail, facsimile, or hand delivery.

The USPTO's latest electronic filing initiative, EFS-Web, was deployed in March 2006. EFS-Web is a web-based patent application and document submission system that allows customers to file applications and associated documents through their standard web browser without downloading special software, changing their documentation preparation tools, or altering their workflow processes. Applicants may create their patent applications and associated documents 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. EFS-Web uses standard web-based screens and prompts. Files are typically submitted through EFS-Web within minutes, depending on the speed of the Internet connection and the size of the PDF files. The USPTO has found that the time required for these submissions is significantly less than that typically required for submissions through the original EFS. In addition, EFS-Web can automatically validate whether the file types and data entered into the web screens meet USPTO standards so that any problems can be corrected before final submission.

At this time, the USPTO is not collecting information for patent term extensions or adjustments electronically, though some follow-on papers may be filed using EFS-Web. As the USPTO expands its electronic filing capabilities, it may become feasible in some cases to allow the public to submit requests for patent term extensions and adjustments electronically. If the USPTO determines that this information can be filed electronically, the USPTO will develop associated electronic forms or formats and submit them to OMB for review and approval as necessary.

The USPTO does currently disseminate some information to the public concerning patent term extensions electronically. The USPTO publishes determinations on applications for

patent term extensions on the USPTO web site as required by the Freedom of Information Act. The USPTO also provides secure access to information about patent applications (including information about patent term adjustments) through the USPTO web site. Online access to application status and history information is available only to authorized individuals, while information for granted patents and published applications is available to the general public.

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 believe 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.

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. This information is not found elsewhere and therefore 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

The 60-Day Notice was published in the *Federal Register* on June 27, 2007 (72 Fed. Reg. 35222). The comment period ended on August 27, 2007. 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 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. 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.

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 to determining the scope of the property right conferred by the patent grant.

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 3 calculates the burden hours and costs of this information collection to the public, based on the following factors:

- Respondent Calculation Factors**
 The USPTO estimates that it will receive approximately 26,859 responses per year as outlined in the table below.
- Burden Hour Calculation Factors**
 The USPTO estimates that it will take the public from one to 25 hours, depending on the complexity and type of filing, to gather the necessary information, prepare the appropriate documents, and submit the applications, petitions, and requests included in this collection.
- Cost Burden Calculation Factors**
 In 2005 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 \$304 per hour used in this submission is the median rate for associate attorneys in private firms as published in that report. The USPTO expects that the information in this collection will be prepared by attorneys. This rate is a fully-loaded hourly rate.

As an illustration of the burden to the public, consider the hour and cost burden on the applicant to file an application for a patent term extension. Based on an average of 25 hours of attorney time at a rate of \$304 per hour, the average cost for an attorney to prepare an application for patent term extension would be \$7,600. While this is a significant amount, it must be taken in the context of the \$300 to \$500 million that an organization may spend to develop a new chemical entity before obtaining approval from the Food and Drug Administration, which would give rise to eligibility for patent term extension. In addition, extension of the term of a patent on a drug product may protect a domestic market worth hundreds of millions, if not billions, of dollars per year.

Table 3: Burden Hour/Cost to Respondents for Patent Term Extensions and Adjustments

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a x b)	Rate (\$/yr) (d)	Total Cost (\$/yr) (e) (d x e)
Application to Extend Patent Term under 35 U.S.C. § 156	25.0	50	1,250	\$304.00	\$380,000.00
Request for Interim Extension under 35 U.S.C. § 156(e)(2)	1.0	1	1	\$304.00	\$304.00
Petition to Review Final Eligibility Decision under 37 CFR 1.750	25.0	1	25	\$304.00	\$7,600.00

Initial Application for Interim Extension under 35 U.S.C. § 156(d)(5)	20.0	1	20	\$304.00	\$6,080.00
Subsequent Application for Interim Extension under 37 CFR 1.790	1.0	1	1	\$304.00	\$304.00
Response to Requirement to Elect	1.0	2	2	\$304.00	\$608.00
Response to Request to Identify Holder of Regulatory Approval	2.0	1	2	\$304.00	\$608.00
Declaration to Withdraw an Application to Extend Patent Term	2.0	1	2	\$304.00	\$608.00
Petition for Reconsideration of Patent Term Adjustment Determination	1.0	24,000	24,000	\$304.00	\$7,296,000.00
Petition for Reinstatement of Reduced Patent Term Adjustment	2.0	2,800	5,600	\$304.00	\$1,702,400.00
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	2.0	1	2	\$304.00	\$608.00
Totals	- - - -	26,859	30,905	- - - - -	\$9,395,120.00

13. Total Annualized Cost Burden

There are no capital start-up, maintenance, or recordkeeping costs associated with this information collection. However, this collection does have annual (non-hour) costs in the form of filing fees and postage costs.

This collection has filing fees associated with the requirements for patent term extension and patent term adjustment. The USPTO estimates that the total filing costs associated with this collection will be \$5,977,040 per year, as outlined in Table 4 below:

Table 4: Filing Costs to Respondents for Patent Term Extensions and Adjustments

Item	Responses (a)	Filing Fees (\$) (b)	Total Non-Hour Cost Burden (c) (a) x (b)
Application to Extend Patent Term under 35 U.S.C. § 156	50	\$1,120.00	\$56,000.00
Request for Interim Extension under 35 U.S.C. § 156(e)(2)	1	\$0.00	\$0.00
Petition to Review Final Eligibility Decision under 37 CFR 1.750	1	\$0.00	\$0.00
Initial Application for Interim Extension under 35 U.S.C. § 156(d)(5)	1	\$420.00	\$420.00
Subsequent Application for Interim Extension under 37 CFR 1.790	1	\$220.00	\$220.00
Response to Requirement to Elect	2	\$0.00	\$0.00
Response to Request to Identify Holder of Regulatory Approval	1	\$0.00	\$0.00
Declaration to Withdraw an Application to Extend Patent Term	1	\$0.00	\$0.00

Petition for Reconsideration of Patent Term Adjustment Determination	24,000	\$200.00	\$4,800,000.00
Petition for Reinstatement of Reduced Patent Term Adjustment	2,800	\$400.00	\$1,120,000.00
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	1	\$400.00	\$400.00
Totals	26,859	\$5,977,040.00

Customers may incur postage costs when submitting the information in this collection to the USPTO by mail. The USPTO estimates that the average first-class postage cost for a mailed submission will be 41 cents and that up to 26,859 submissions will be mailed to the USPTO per year. The total estimated postage cost for this collection is \$11,012 per year.

The total annual (non-hour) cost burden for this collection in the form of filing fees (\$5,977,040) and postage costs (\$11,012) is \$5,988,052 per year.

14. Annual Cost to the Federal Government

The USPTO estimates that it takes a GS-5, step 1 employee between 15 minutes and 2 hours to process the various applications, petitions, and requests associated with patent term extensions and patent term adjustments, depending upon the situation. The hourly rate for a GS-5, step 1 employee is currently \$14.56. When 30% is added to account for a fully-loaded hourly rate (benefits and overhead), the hourly rate for a GS-5, step 1 is \$14.56 + \$4.37, for a rate of \$18.93.

Table 5 calculates the burden hours and costs of this information collection to the Federal Government:

Table 5: Burden Hour/Cost to the Federal Government for Patent Term Extensions and Adjustments

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a x b)	Rate (\$/yr) (d)	Total Cost (\$/yr) (e) (d x e)
Application to Extend Patent Term under 35 U.S.C. § 156	2.00	50	100	\$18.93	\$1,893.00
Request for Interim Extension under 35 U.S.C. § 156(e)(2)	0.50	1	1	\$18.93	\$19.00
Petition to Review Final Eligibility Decision under 37 CFR 1.750	0.25	1	1	\$18.93	\$19.00
Initial Application for Interim Extension under 35 U.S.C. § 156(d)(5)	0.50	1	1	\$18.93	\$19.00
Subsequent Application for Interim Extension under 37 CFR 1.790	0.50	1	1	\$18.93	\$19.00
Response to Requirement to Elect	0.25	2	1	\$18.93	\$19.00
Response to Request to Identify Holder of Regulatory Approval	0.25	1	1	\$18.93	\$19.00

Declaration to Withdraw an Application to Extend Patent Term	0.25	1	1	\$18.93	\$19.00
Petition for Reconsideration of Patent Term Adjustment Determination	1.00	24,000	24,000	\$18.93	\$454,320.00
Petition for Reinstatement of Reduced Patent Term Adjustment	1.00	2,800	2,800	\$18.93	\$53,004.00
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	0.25	1	1	\$18.93	\$19.00
Totals	- - - -	26,859	26,908	- - - -	\$509,369.00

15. Reason for Change in Burden

Summary of Changes Since the Previous Renewal

This information collection was previously approved by OMB in October 2004 with a total of 26,859 responses and 30,905 burden hours per year. For this renewal, the USPTO is maintaining these burden estimates for annual responses and hours.

The total annual (non-hour) cost burden for this renewal of \$5,988,052 is an increase of \$1,074 from the currently approved total of \$5,986,978 in annual costs for this collection. This increase is due to administrative adjustments.

Change in Respondent Cost Burden

This collection was previously approved using an estimated hourly rate of \$286 for attorneys preparing the information in this collection. At the current estimated rate of \$304 per hour for attorneys, the 30,905 burden hours estimated for this renewal yield a respondent cost burden of \$9,395,120, which is an increase of \$556,290 over the currently approved burden of \$8,838,830. This increase in respondent cost burden is due to the increase in the estimated hourly rate for attorneys from \$286 to \$304.

Changes in Responses and Burden Hours

For this renewal, the USPTO estimates that there will be no change in the total responses and burden hours from the currently approved burden for this collection.

Changes in Annual (Non-hour) Costs

For this renewal, the USPTO estimates that the total annual (non-hour) costs will increase by \$1,074, from \$5,986,978 to \$5,988,052 per year. This increase is due to revising the estimated postage costs for submitting the information in this collection to the USPTO by mail. **Therefore, this collection has an increase in annual (non-hour) cost burden of \$1,074 due to an administrative adjustment.**

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-Patents (Official Gazette-Patents)*. 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-Patents*. The *Official Gazette-Patents* is published in electronic format on the USPTO web site.

17. Display of Expiration Date of OMB Approval

There are no forms associated with this collection. Therefore, the display of the expiration date is not applicable.

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.

REFERENCES

- A. The USPTO Information Quality Guidelines
- B. 60-Day Notice published in the *Federal Register* on June 27, 2007 (72 Fed. Reg. 35222)