

**SUPPORTING STATEMENT**  
**United States Patent and Trademark Office**  
**Patent Term Extension**  
**OMB CONTROL NUMBER 0651-0020**  
**(July 2010)**

**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.

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 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 through 37 CFR 1.701-1.705.

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)
Request for Recalculation of Patent Term Adjustment in View of <i>Wyeth</i>	35 U.S.C. 154(b)(2)(A)	37 CFR 1.705

## 2. Needs and Uses

The public uses this information collection to file requests related to patent term extensions 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 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"> <li>Used by the public to apply for a patent term extension.</li> <li>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.</li> </ul>
Request for Interim Extension under 35 U.S.C. 156(e)(2)	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to request an interim extension.</li> <li>Used by the USPTO to trigger an interim extension before processing of the application has been completed.</li> </ul>
Petition to Review Final Eligibility Decision under 37 CFR 1.750	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to petition the USPTO to review final eligibility decisions.</li> <li>Used by the USPTO to review final eligibility decisions, as long as the petition is filed within a set time.</li> </ul>
Initial Application for Interim Extension under 35 U.S.C. 156(d)(5)	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to apply for an interim extension.</li> <li>Used by the USPTO to determine eligibility of a patent for interim extension.</li> </ul>
Subsequent Application for Interim Extension under 35 CFR 1.790	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to apply for a subsequent interim extension.</li> <li>Used by the USPTO to determine eligibility of a patent for subsequent interim extension.</li> </ul>
Response to Requirement to Elect	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to elect which patent of more than one patent to extend.</li> <li>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.</li> </ul>
Response to Request to Identify Holder of Regulatory Approval	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to declare eligibility to apply for a patent term extension.</li> <li>Used by the USPTO to determine eligibility of patent owner to obtain an extension of a patent.</li> </ul>
Declaration to Withdraw an Application to Extend Patent Term	No Form Associated	<ul style="list-style-type: none"> <li>Used by the public to withdraw an application to extend a patent term.</li> <li>Used by the USPTO to avoid extending patents that the patent owner no longer seeks to extend.</li> </ul>
Petition for Reconsideration of Patent Term Adjustment Determination	No Form Associated	<ul style="list-style-type: none"> <li>Used by the patentee to correct errors in the USPTO's patent term adjustment determination.</li> <li>Used by the USPTO to determine whether its patent term adjustment determination is in error.</li> <li>Used by the USPTO to determine the correct patent term adjustment.</li> </ul>

Petition for Reinstatement of Reduced Patent Term Adjustment	No Form Associated	<ul style="list-style-type: none"> <li>Used by the patentee to request reinstatement of reduced patent term adjustment.</li> <li>Used by the USPTO to determine whether the patentee is entitled to reinstatement of reduced patent term adjustment.</li> </ul>
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"> <li>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.</li> <li>Used by the USPTO to determine the filing date for an application for extension of a patent term.</li> </ul>
Request for Recalculation of Patent Term Adjustment in View of <i>Wyeth</i>	PTO/SB/131	<ul style="list-style-type: none"> <li>Used by the patentee to request a revised patent term adjustment based solely on the USPTO's pre-<i>Wyeth</i> interpretation of 35 U.S.C. 154(b)(2)(A).</li> <li>Used by the USPTO to determine the correct patent term adjustment.</li> </ul>

### 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 is a document submission system that 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. The USPTO also provides fillable PDF forms, such as the Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131), that can be submitted through EFS-Web. These forms may be downloaded from the USPTO Web site and do not require special PDF creation software.

Registered and unregistered users can file documents securely through EFS-Web, which is hosted on secure servers. 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. After the document has been successfully submitted through EFS-Web, customers will receive an acknowledgement receipt that lists the time and date stamp stating when the document was submitted to the USPTO, an application number, a confirmation number, and other critical information, such as the EFS ID, a listing of the files and documents associated with the submission, and page counts for the files and documents. This receipt is the legal equivalent of a postcard in the postcard receipt practice used for patent application documents that are filed in paper. The USPTO

recommends that customers print the electronic acknowledgement receipt to keep with their records.

There are many additional benefits to filing through EFS-Web. 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.

#### **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 April 20, 2010 (75 Fed. Reg. 20561). The comment period ended on June 21, 2010. 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 required to provide the information 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.

**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 13,586 responses per year as outlined in the table below.
- **Burden Hour Calculation Factors**  
The USPTO estimates that it will take the public from 10 minutes (0.17 hours) to 25 hours, depending on the complexity and type of filing, to gather the necessary information, prepare the appropriate documents, and submit the information in this collection to the USPTO.
- **Cost Burden Calculation Factors**  
In 2009 the Committee on Economics of Legal Practice of the American Intellectual Property Law Association published a report that summarized the results of a survey with data on hourly billing rates. The professional rate of \$325 per hour used in this submission is the median rate for attorneys in private firms as published in that report. The USPTO expects that the information in this collection will be prepared by attorneys. This estimate is a fully-loaded hourly rate.

**Table 3: Burden Hour/Burden 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	40	1,000	\$325.00	\$325,000.00
Request for Interim Extension under 35 U.S.C. 156(e)(2)	1.0	1	1	\$325.00	\$325.00
Petition to Review Final Eligibility Decision under 37 CFR 1.750	25.0	3	75	\$325.00	\$24,375.00

Initial Application for Interim Extension under 35 U.S.C. 156(d)(5)	20.0	3	60	\$325.00	\$19,500.00
Subsequent Application for Interim Extension under 37 CFR 1.790	1.0	1	1	\$325.00	\$325.00
Response to Requirement to Elect	1.0	5	5	\$325.00	\$1,625.00
Response to Request to Identify Holder of Regulatory Approval	2.0	1	2	\$325.00	\$650.00
Declaration to Withdraw an Application to Extend Patent Term	2.0	1	2	\$325.00	\$650.00
Petition for Reconsideration of Patent Term Adjustment Determination	3.0	1,500	4,500	\$325.00	\$1,462,500.00
Petition for Reinstatement of Reduced Patent Term Adjustment	4.0	30	120	\$325.00	\$39,000.00
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	2.0	1	2	\$325.00	\$650.00
Request for Recalculation of Patent Term Adjustment in View of <i>Wyeth</i> (PTO/SB/131)	0.17	12,000	2,040	\$325.00	\$663,000.00
<b>Totals</b>	- - - -	<b>13,586</b>	<b>7,808</b>	- - - -	<b>\$2,537,600.00</b>

### 13. Total Annualized (Non-hour) Cost Burden

There are no capital start-up or maintenance costs associated with this information collection. However, this collection does have annual (non-hour) costs in the form of filing fees, postage costs, and recordkeeping 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 fees associated with this collection will be \$358,680 per year, as outlined in Table 4 below:

**Table 4: Filing Fees 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	40	\$1,120.00	\$44,800.00
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	3	\$0.00	\$0.00
Initial Application for Interim Extension under 35 U.S.C. 156(d)(5)	3	\$420.00	\$1,260.00
Subsequent Application for Interim Extension under 37 CFR 1.790	1	\$220.00	\$220.00
Response to Requirement to Elect	5	\$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	1,500	\$200.00	\$300,000.00
Petition for Reinstatement of Reduced Patent Term Adjustment	30	\$400.00	\$12,000.00
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
Request for Recalculation of Patent Term Adjustment in View of <i>Wyeth</i> (PTO/SB/131)	12,000	\$0.00	\$0.00
<b>Totals</b>	<b>13,586</b>	<b>.....</b>	<b>\$358,680.00</b>

Customers may incur postage costs when submitting the information in this collection to the USPTO by mail. The USPTO expects that the Application to Extend Patent Term under 35 U.S.C. 156, the Initial Application for Interim Extension under 35 U.S.C. 156(d)(5), and approximately 7% of the other responses for this collection will be submitted by mail. The USPTO estimates that the average first-class postage cost for these 991 mailed submissions will be 44 cents each, for a total estimated postage cost of \$436 per year.

When submitting the information in this collection to the USPTO electronically, the customer is strongly urged to retain a copy of the acknowledgment receipt as evidence that the submission was received by the USPTO on the date noted. The USPTO estimates that it will take 2 minutes (0.03 hours) to print and retain a copy of the acknowledgment receipt and that approximately 12,595 responses per year will be submitted electronically, for a total of approximately 378 hours per year for printing this receipt. Using the paraprofessional rate of \$100 per hour, the USPTO estimates that the recordkeeping cost associated with this collection will be \$37,800 per year.

**The total annual (non-hour) cost burden for this collection in the form of filing fees (\$358,680), postage costs (\$436), and recordkeeping costs (\$37,800), is \$396,916 per year.**

#### **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 various applications, petitions, and requests associated with patent term extensions and adjustments. The hourly rate for a GS-5, step 1 employee is currently \$16.33. When 30% is added to account for a fully-loaded hourly rate (benefits and overhead), the hourly rate for a GS-5, step 1 employee is \$21.23 (\$16.33 + \$4.90).

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

**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	40	80	\$21.23	\$1,698.00
Request for Interim Extension under 35 U.S.C. 156(e)(2)	0.50	1	1	\$21.23	\$21.00
Petition to Review Final Eligibility Decision under 37 CFR 1.750	0.25	3	1	\$21.23	\$21.00
Initial Application for Interim Extension under 35 U.S.C. 156(d)(5)	0.50	3	2	\$21.23	\$42.00
Subsequent Application for Interim Extension under 37 CFR 1.790	0.50	1	1	\$21.23	\$21.00
Response to Requirement to Elect	0.25	5	1	\$21.23	\$21.00
Response to Request to Identify Holder of Regulatory Approval	0.25	1	1	\$21.23	\$21.00
Declaration to Withdraw an Application to Extend Patent Term	0.25	1	1	\$21.23	\$21.00
Petition for Reconsideration of Patent Term Adjustment Determination	1.00	1,500	1,500	\$21.23	\$31,845.00
Petition for Reinstatement of Reduced Patent Term Adjustment	1.00	30	30	\$21.23	\$637.00
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	0.25	1	1	\$21.23	\$21.00
Request for Recalculation of Patent Term Adjustment in View of <i>Wyeth</i> (PTO/SB/131)	0.10	12,000	1,200	\$21.23	\$25,476.00
<b>Totals</b>	- - - -	<b>13,586</b>	<b>2,819</b>	- - - -	<b>\$59,845.00</b>

## 15. Reason for Change in Burden

### Summary of Changes Since the Previous Renewal

This information collection was previously approved by OMB in February 2008 with a total of 26,859 responses and 30,905 burden hours per year. OMB also approved an emergency clearance for the Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131) in January 2010, which added 12,000 responses and 2,040 hours for a total burden of 38,859 responses and 32,945 hours for this collection.

For this renewal, the USPTO estimates that the total annual responses will be 13,586 and the total annual burden hours will be 7,808, which is a decrease of 25,273 responses and 25,137 hours from the currently approved burden for this collection. This decrease in burden hours is due to administrative adjustments. In addition, the USPTO estimates that

the proportion of responses submitted electronically will be approximately 93%, an increase from the previous estimate of 29%.

The total annual (non-hour) cost burden for this renewal of \$396,916 is a decrease of \$5,592,606 from the currently approved total of \$5,989,522 in annual costs for this collection. This decrease in annual costs is due to administrative adjustments.

#### Changes from the 60-Day Notice

Since the 60-Day Notice for this renewal was published, the USPTO has revised the estimated time for recordkeeping associated with electronic submissions from 5 seconds (0.001 hours) to 2 minutes (0.03 hours) per response for printing and retaining the acknowledgment receipt, increasing the total recordkeeping hours for this collection from 13 to 378 and the associated costs from \$1,300 to \$37,800 per year. Consequently, the total estimated annual (non-hour) cost burden has been increased from \$360,416 to \$396,916 due to the increase in estimated recordkeeping costs.

#### Change in Respondent Cost Burden

This collection was previously approved in February 2008 using an estimated hourly rate of \$304 for attorneys preparing the information, which yields a respondent cost burden of \$10,015,280 for the currently approved 32,945 burden hours. At the current estimated rate of \$325 per hour for attorneys, the 7,808 burden hours estimated for this renewal yield a respondent cost burden of \$2,537,600, which is a decrease of \$7,477,680. This decrease in respondent cost burden is primarily due to the decrease in total burden hours for the collection, despite the increase in the estimated hourly rate for attorneys from \$304 to \$325.

#### Changes in Responses and Burden Hours

For this renewal, the USPTO estimates that the total annual responses for this collection will decrease by 25,273 and the total annual burden hours will decrease by 25,137. This decrease in burden hours is due to administrative adjustments, as follows:

- The USPTO is adjusting the estimated annual responses for the Application to Extend Patent Term under 35 U.S.C. 156 to 40, which is a decrease of 10 from the previous estimate of 50. **Therefore, this collection takes a burden decrease of 250 hours as an administrative adjustment.**
- The USPTO is adjusting the estimated annual responses for the Petition to Review Final Eligibility Decision under 37 CFR 1.750 to 3, which is an increase of 2 from the previous estimate of 1. **Therefore, this collection takes a burden increase of 50 hours as an administrative adjustment.**

- The USPTO is adjusting the estimated annual responses for the Initial Application for Interim Extension under 35 U.S.C. 156(d)(5) to 3, which is an increase of 2 from the previous estimate of 1. **Therefore, this collection takes a burden increase of 40 hours as an administrative adjustment.**
- The USPTO is adjusting the estimated annual responses for the Response to Requirement to Elect to 5, which is an increase of 3 from the previous estimate of 2. **Therefore, this collection takes a burden increase of 3 hours as an administrative adjustment.**
- The USPTO is adjusting the estimated annual responses for the Petition for Reconsideration of Patent Term Adjustment Determination to 1,500, which is a decrease of 22,500 from the previous estimate of 24,000. The USPTO has also revised the time estimate for preparing this petition, increasing the estimate from 1 hour to 3 hours per response. **Therefore, this collection takes a burden decrease of 19,500 hours as an administrative adjustment.**
- The USPTO is adjusting the estimated annual responses for the Petition for Reinstatement of Reduced Patent Term Adjustment to 30, which is a decrease of 2,770 from the previous estimate of 2,800. The USPTO has also revised the time estimate for preparing this petition, increasing the estimate from 2 hours to 4 hours per response. **Therefore, this collection takes a burden decrease of 5,480 hours as an administrative adjustment.**
- The USPTO does not expect any changes in the estimated annual responses or burden hours for the remaining items in the collection.

**In sum, this information collection has a total burden decrease of 25,137 hours due to administrative adjustments.**

#### Changes in Annual (Non-hour) Costs

For this renewal, the USPTO estimates that the total annual (non-hour) costs will decrease by \$5,592,606. This decrease in annual (non-hour) costs is due to administrative adjustments, as follows:

- This collection was previously approved with a total of \$5,977,040 in fees. For this renewal, total estimated fees have decreased to \$358,680 due to overall decreases in the estimated number of responses for items in this collection that have fees. **Therefore, this collection takes a decrease of \$5,618,360 in annual (non-hour) costs as an administrative adjustment.**
- This collection was previously approved with a total of \$11,382 in postage costs. For this renewal, total estimated postage costs have decreased to \$436 primarily

due to a decrease in the estimated number of responses being submitted by mail. **Therefore, this collection takes a decrease of \$10,946 in annual (non-hour) costs as an administrative adjustment.**

- This collection was previously approved with a total of \$1,100 in recordkeeping costs. For this renewal, total estimated recordkeeping costs have increased to \$37,800 due to an increase in the estimated number of responses submitted electronically and an adjustment to the estimated recordkeeping time required per response. **Therefore, this collection takes an increase of \$36,700 in annual (non-hour) costs as an administrative adjustment.**

**In sum, this collection has a total decrease in annual (non-hour) cost burden of \$5,592,606 due to administrative adjustments.**

#### **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**

The form in this information collection will 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.

## REFERENCES

- A. The USPTO Information Quality Guidelines
- B. Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131)
- B. 60-Day Notice published in the *Federal Register* on April 20, 2010 (75 Fed. Reg. 20561)