



DEPARTMENT OF COMMERCE

**Patent and Trademark Office**

**Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Patent Term Extension and Adjustment**

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

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** The United States Patent and Trademark Office (hereafter “USPTO” or “Agency”), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0020 (Patent Term Extension and Adjustment). The purpose of this notice is to allow 60 days for public comments preceding submission of the information collection to Office of Management and Budget (OMB).

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

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

- Email: [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include “0651-0020 comment” in the subject line of the message.

- Federal eRulemaking Portal: <http://www.regulations.gov>.
- Mail: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- Telephone: Jeffrey West, Senior Legal Advisor, 571-272-2226.
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**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to: Jeffrey West, Senior Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; 571-272-7728; or [jeffrey.west@uspto.gov](mailto:jeffrey.west@uspto.gov) with “0651-0020 comment” in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

## **SUPPLEMENTARY INFORMATION:**

### **I. Abstract**

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 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.

Apart 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 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.

## **II. Method of Collection**

Items in this information collection may be submitted electronically, by mail, or by hand delivery to the USPTO.

## **III. Data**

*OMB Control Number:* 0651-0020.

*Forms:* None.

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

*Affected Public:* Private sector.

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

*Frequency:* On occasion.

*Estimated Number of Annual Respondents:* 903 respondents.

*Estimated Number of Annual Responses:* 903 responses.

*Estimated Time per Response:* The USPTO estimates that the responses in this information collection will take the public approximately 1 to 25 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item(s) to the USPTO.

*Estimated Total Annual Respondent Burden Hours:* 6,807 hours.

*Estimated Total Annual Respondent Hourly Cost Burden:* \$3,042,729.

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

Item No.	Item Name	Estimated Annual Respondents	Respondents per Respondent	Estimated Annual Responses	Estimated Time per Response (hours)	Estimated Burden (hour/year)	Rate <sup>1</sup> (\$/hour)	Estimated Annual Respondent Cost Burden
		(a)	(b)	(a) x (b) = (c)	(d)	(c) x (d) = (e)	(f)	(e) x (f) = (g)
1	Application to Extend Patent Term Under 35 U.S.C. 156	134	1	134	25	3,350	\$447	\$1,497,450
2	Request for Interim Extension Under 35 U.S.C. 156(e)(2)	24	1	24	1	24	\$447	\$10,728
3	Petition to review final Eligibility Decision Under 37 CFR 1.750	56	1	56	25	1,400	\$447	\$625,800
4	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	4	1	4	20	80	\$447	\$35,760
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	3	1	3	1	3	\$447	\$1,341
6	Response to Requirement to Elect a Single Patent to Extend from a Single Regulatory Review Period	38	1	38	1	38	\$447	\$16,986
7	Response to Request to Identify Holder of Regulatory Approval	19	1	19	2	38	\$447	\$16,986

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

Item No.	Item Name	Estimated Annual Respondents (a)	Respondents per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate <sup>1</sup> (\$/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
8	Declaration to Withdraw an Application to Extend Patent Term	1	1	1	2	2	\$447	\$894
9	Petition for Reconsideration of Patent Term Adjustment Determination	622	1	622	3	1,866	\$447	\$834,102
10	Petition for Reinstatement of Reduced Patent Term Adjustment	1	1	1	4	4	\$447	\$1,788
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	\$447	\$894
	<b>Totals</b>	<b>903</b>	<b>---</b>	<b>903</b>	<b>---</b>	<b>6,807</b>	<b>---</b>	<b>\$3,042,729</b>

*Estimated Total Annual Respondent Non-hourly Cost Burden:* \$489,431. There are no capital startup costs, maintenance costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual non-hourly cost burden for this information collection, in the form of filing fees and postage, is \$489,431.

### Filing Fees

The items with filing fees are listed in the table below.

**Table 2: Filing Fees**

Item No.	Fee Code(s)	Item	Annual Estimated Responses	Filing Fee	Total Cost
1	1457/2457/3457	Application to Extend Patent Term Under 35 U.S.C. 156	134	\$2,500	\$335,000
4	1458/2458/3458	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	4	\$1,320	\$5,280

<b>Item No.</b>	<b>Fee Code(s)</b>	<b>Item</b>	<b>Annual Estimated Responses</b>	<b>Filing Fee</b>	<b>Total Cost</b>
5	1459/2459/3459	Subsequent Application for Interim Extension Under 37 CFR 1.790	3	\$680	\$2,040
9	1455/2455/3455	Petition for Reconsideration of Patent Term Adjustment Determination	622	\$226	\$140,572
9	1465/2465/3465	Supplemental Redetermination After Notice of Final Determination	4	\$1,440	\$5,760
10	1456/2456/3456	Petition for Reinstatement of Reduced Patent Term Adjustment	1	\$452	\$452
11	1455/2455/3455	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	1	\$226	\$226
		<b>Totals</b>	<b>769</b>	<b>---</b>	<b>\$489,330</b>

### 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. The USPTO estimates that 1% of the 903 items in this information collection will be submitted in the mail, resulting in 9 mailed items. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail legal flat-rate envelope, will be \$11.20. Therefore, the USPTO estimates the total mailing costs for this information collection at \$101.

### **IV. Request for Comments**

The USPTO is soliciting public comments to:

- (a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected; and
- (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

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

**Justin Isaac,**

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

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