



DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Patent Term Extension

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. § 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: InformationCollection@uspto.gov. Include "0651-0020 comment" in the subject line of the message.
- Mail: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.
- Federal Rulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-7728; or by e-mail to Raul.Tamayo@uspto.gov. Additional information about this 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 (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 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.

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 USPTO is updating this information collection to remove one item, the Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131), because the information is no longer being collected. The USPTO is also removing the fees associated with the information requirements in this collection because these fees have been moved into information collection 0651-0072, which was approved by OMB in January 2013 in conjunction with the USPTO rulemaking "Setting and Adjusting Patent Fees" (RIN 0651-AC54).

II. Method of Collection

By mail, facsimile, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651-0020.

Form Number(s): None.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 1,950 responses per year. The USPTO estimates that approximately 25% of these responses will be from small entities.

Estimated Time Per Response: The USPTO estimates that it will take the public from 1 to 25 hours, depending on the complexity of the situation, to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 7,252 hours.

Estimated Total Annual Respondent Cost Burden: \$2,690,492. The USPTO expects that the information in this collection will be prepared by attorneys at an estimated

rate of \$371 per hour. Therefore, the USPTO estimates that the respondent cost burden for this collection will be approximately \$2,690,492 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Application to Extend Patent Term Under 35 U.S.C. § 156	25 hours	60	1,500
Request for Interim Extension Under 35 U.S.C. § 156(e) (2)	1 hour	10	10
Petition to Review Final Eligibility Decision Under 37 CFR 1.750	25 hours	3	75
Initial Application for Interim Extension Under 35 U.S.C. § 156(d) (5)	20 hours	3	60
Subsequent Application for Interim Extension Under 37 CFR 1.790	1 hour	1	1
Response to Requirement to Elect	1 hour	10	10
Response to Request to Identify Holder of Regulatory Approval	2 hours	1	2
Declaration to Withdraw an Application to Extend Patent Term	2 hours	1	2
Petition for Reconsideration of Patent Term Adjustment Determination	3 hours	1,850	5,550
Petition for Reinstatement of Reduced Patent Term Adjustment	4 hours	10	40
Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	2 hours	1	2
Totals	1,950	7,252

Estimated Total Annual Non-hour Respondent Cost Burden: \$90. 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 postage costs.

There are fees associated with the requirements for patent term extension and patent term adjustment. These fees are covered under OMB control number 0651-0072. The fees are listed in the accompanying table for reference but will not be included in the annual (non-hour) cost burden for this collection.

Item	Fee amount
Application to Extend Patent Term Under 35 U.S.C. § 156	\$1,120.00
Request for Interim Extension Under 35 U.S.C. § 156(e) (2)	\$0.00
Petition to Review Final Eligibility Decision Under 37 CFR 1.750	\$0.00
Initial Application for Interim Extension Under 35 U.S.C. § 156(d) (5)	\$420.00
Subsequent Application for Interim Extension Under 37 CFR 1.790	\$220.00
Response to Requirement to Elect	\$0.00
Response to Request to Identify Holder of Regulatory Approval	\$0.00
Declaration to Withdraw an Application to Extend Patent Term	\$0.00
Petition for Reconsideration of Patent Term Adjustment Determination	\$200.00
Petition for Reinstatement of Reduced Patent Term Adjustment	\$400.00
Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	(large entity) \$400.00 (small entity) \$200.00 (micro entity) \$100.00

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 a mailed submission will be 46 cents and that up to 195 submissions will be mailed to the USPTO per year, for a total estimated postage cost of \$90 per year.

The total annual (non-hour) respondent cost burden for this collection is estimated to be approximately \$90 per year.

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

The USPTO is soliciting public comments to:

(a) Evaluate whether the proposed 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 proposed 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.

Dated: May 22, 2013

Susan K. Fawcett,
Records Officer, USPTO,
Office of the Chief Information Officer.

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