

J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting dates.

Dated: May 25, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

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 August 2, 2004.

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

- E-mail: Susan.Brown@uspto.gov. Include "0651-0020 comment" in the subject line of the message.
- Fax: 703-308-7407, marked to the attention of Susan Brown.

- Mail: Susan K. Brown, Records Officer, Office of the Chief Information Officer, Office of Data Architecture and Services, Data Administration Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Robert J. Spar, Director, Office of Patent Legal Administration, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 703-308-5107; or by e-mail at Bob.Spar@uspto.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

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 to a communication from the USPTO within three months of the mailing date of the communication. 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 subpart F (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 which 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.

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.

This collection was previously approved by OMB in October 2001. The USPTO also submitted this collection in conjunction with a notice of proposed rulemaking entitled "Changes to Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan" (RIN 0651-AB64), which was published in the **Federal Register** on September 12, 2003 (vol. 68, no. 177). The proposed rulemaking increased the filing fee for the Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term, which was added to this collection. The proposed rulemaking would also allow applicants to use electronic signatures to sign documents that have been created with a word processor. The information collection package for 0651-0020 associated with this proposed rulemaking was approved by OMB in November 2003. The proposed changes related to patent term adjustments were finalized in the final rule notice entitled "Revision of Patent Term Extension and Patent Term Adjustment Provisions" (RIN 0651-AB71), which was published in the **Federal Register** on April 22, 2004.

II. Method of Collection

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

III. Data

OMB Number: 0651-0020.

Form Number(s): None.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; not-for-profit institutions; farms; the Federal government; and State, local or tribal governments.

Estimated Number of Respondents: 26,859 responses per year.

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 applications, requests, and petitions included in this collection.

Estimated Total Annual Respondent Burden Hours: 30,905 hours per year.
Estimated Total Annual Respondent Cost Burden: \$8,838,830 per year. The USPTO expects that the information in this collection will be prepared by

attorneys. Using the professional rate of \$286 per hour for associate attorneys in private firms, the USPTO estimates that the respondent cost burden for submitting the information in this collection will be \$8,838,830 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	50	1,250
Request for Interim Extension under 35 U.S.C. 156(e)(2)	1	1	1
Petition to Review Final Eligibility Decision under 37 CFR 1.750	25	1	25
Initial Application for Interim Extension under 35 U.S.C. 156(d)(5)	20	1	20
Subsequent Application for Interim Extension under 37 CFR 1.790	1	1	1
Response to Requirement to Elect	1	2	2
Response to Request to Identify Holder of Patent Term	2	1	2
Declaration to Withdraw an Application to Extend Patent Term	2	1	2
Petition for Reconsideration of Patent Term Adjustment Determination	1	24,000	24,000
Petition for Reinstatement of Reduced Patent Term Adjustment	2	2,800	5,600
Petition to Accord a Filing Date to an Application under 37 CFR 1.740 for Extension of a Patent Term	2	1	2
TOTAL		26,859	30,905

Estimated Total Annual Non-hour Respondent Cost Burden: \$5,986,978 per year. 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.

Item	Estimated annual responses	Fee amount	Estimated annual filing costs
Application to Extend Patent Term under 35 U.S.C. 156	50	\$1,120.00	\$56,000.00
Request for Interim Extension 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 Patent Term	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
TOTAL	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 37 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 \$9,938 per year.

The total non-hour respondent cost burden for this collection in the form of filing fees and postage costs is \$5,986,978 per year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have

practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, e.g., the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 24, 2004.

Susan K. Brown,

Records Officer, USPTO, Office of the Chief Information Officer, Office of Data Architecture and Services, Data Administration Division.

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