JUSTIFICATION FOR NONMATERIAL/NONSUBSTANTIVE CHANGES
Patent Term Extension and Adjustment
0651-0020

Background

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.

In support of RIN 0651-AD64 (Setting and Adjusting Patent Fees During Fiscal Year 2025; 89 FRN 91898)[1], the USPTO is changing six fees and adding one fee in this information collection.

Table 1: Changes in Fee Amount

Item No.	Fee Code	Item	Current Fee	New Fee	Changes in Fee Amount
1	1457/2457/3457	Application to Extend Patent Term Under 35 U.S.C. 156	$1,180	$2,500	+$1,320
4	1458/2458/3458	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	$440	$1,320	+$880
5	1459/2459/3459	Subsequent Application for Interim Extension Under 37 CFR 1.790	$230	$680	+$450

[1] https://www.govinfo.gov/content/pkg/FR-2024-11-20/pdf/2024-26821.pdf

9	1455/2455/3455	Petition for Reconsideration of Patent Term Adjustment Determination	$210	$226	+$16
9	14SR/24SR/34SR	Supplemental redetermination after notice of final determination	Not previously included in 0651-0020, new	$1,440	$1,440
10	1456/2456/3456	Petition for Reinstatement of Reduced Patent Term Adjustment	$420	$452	+$32
11	1455/2455/3455	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	$210[2]	$226	+$16

Table 2: Proposed Burden

Item No.	Fee Code	Item	Reponses (a)	New Fee (b)	New Non-hour Cost Burden (a) x (b) = (c)
1	1457/2457/3457	Application to Extend Patent Term Under 35 U.S.C. 156	150	$2,500	$375,000
4	1458/2458/3458	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	10	$1,320	$13,200
5	1459/2459/3459	Subsequent Application for Interim Extension Under 37 CFR 1.790	10	$680	$6,800
9	1455/2455/3455	Petition for Reconsideration of Patent Term Adjustment Determination	650	$226	$146,900
9	14SR/24SR/34SR	Supplemental redetermination after notice of final determination	5	$1,440	$7,200
10	1456/2456/3456	Petition for Reinstatement of Reduced Patent Term Adjustment	15	$452	$6,780
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
		Totals	**841**	**- - -**	**$556,106**

Table 3: Changes in Cost

Item No.	Fee Code	Items	Current Cost (a)	New Cost (b)	Change in Non-hour Cost Burden (b) – (a) = (c)
1	1457/2457/3457	Application to Extend Patent Term Under 35 U.S.C. 156	$177,000	$375,000	+$198,000
4	1458/2458/3458	Initial Application for Interim Extension Under 35 U.S.C. 156(d)(5)	$4,400	$13,200	+$8,800
5	1459/2459/3459	Subsequent Application for Interim Extension Under 37 CFR 1.790	$2,300	$6,800	+$4,500
9	1455/2455/3455	Petition for Reconsideration of Patent Term Adjustment Determination	$136,500	$146,900	+$10,400

[2] The 2023 supporting statement for this information collection listed the cost of this fee incorrectly valued at $420. This change worksheet uses the correct value for this fee.

9	14SR/24SR/34SR	Supplemental redetermination after notice of final determination	Not previously included in 0651-0020, new	$7,200	+$7,200
10	1456/2456/3456	Petition for Reinstatement of Reduced Patent Term Adjustment	$6,300	$6,780	+$480
11	1455/2455/3455	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	$210[3]	$226	+$16
		Totals	**$326,710**	**$556,106**	**+$229,396**

Summary of Changes

The aforementioned rulemaking results in the revision of six fees and the introduction of one fee, with an increase of $229,103 in annual non-hourly costs to collection 0651-0020.

Changes in Burden

Burden Type	Currently Approved	Proposed Change[4]	New Estimate
Non-hourly Cost Burden	$327,003	+$229,103	$556,106

0651-0016's revised burden is as follows:

- 915 annual responses (unchanged)
- 6,038 annual hourly burden (unchanged)
- $556,106 in annual non-hourly burden costs

[3] The 2023 supporting statement for this information collection listed the cost of this fee incorrectly valued at $420. This change worksheet uses the correct value for this fee, resulting in a slightly lower proposed change value than would be expected.
[4] See comment above.