**JUSTIFICATION FOR NONMATERIAL/NONSUBSTANTIVE CHANGE**

**Requirements for Patent Applications Containing Nucleotide Sequence and Amino Acid Sequence Disclosure**

**OMB Control Number 0651-0024**

Background

The United States Patent and Trademark Office (UPSTO) administers the Leahy-Smith America Invents Act (AIA), Section 10, which sets or adjusts patent fees established authorized, or charged under Title 35, United States Code (U.S.C.). Section 10 prescribes that fees may be set or adjusted only to recover the aggregate estimated costs to the Office for processing, activities, services, and materials related to patent. Section 10 authorities also includes flexibility to set individual fees in a way that furthers key policies factors, while taking into account the cost of the respective services.

The request is to update the fees attached to this collection that are affected by the rulemaking NPRM 0651-AD02, and also to incorporate fees were not counted in pervious approvals. Respondent numbers are also changing due to agency discretion in conjunction with the rule.

There are two fees being introduced as a result of the 2017 Patent Biennial Fee Review.

**Table 1: Total Fee and Respondent Increases**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IC #** | **Item** | **Updated Responses** | **Updated Fee** | **Updated Non-hour Burden ($)** |
| 1 | Submissions of sequence listings of 300MB to 800 MB (large entity) | 6 | $1,000.00 | $6,000.00 |
| 1 | Submissions of sequence listings of 300MB to 800 MB (small entity) | 2 | $500.00 | $1,000.00 |
| 1 | Submissions of sequence listings of 300MB to 800 MB (micro entity) | 1 | $250.00 | $250.00 |
| 1 | Submissions of sequence listings of more than 800 MB (large entity) | 2 | $10,000.00 | $20,000.00 |
| 1 | Submissions of sequence listings of more than 800 MB (small entity) | 1 | $5,000.00 | $5,000.00 |
| 1 | Submissions of sequence listings of more than 800 MB (micro entity) | 1 | $2,500.00 | $2,500.00 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (large entity) | 247 | $300.00 | $74,100.00 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (small entity) | 50 | $150.00 | $7,500.00 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (micro entity) | 5 | $75.00 | $375.00 |
|  | **Totals** | **315** |  | **$116,725.00** |

**Table 2: Increases in Fee Amount**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IC #** | **Item** | **Current Fee** | **Proposed Fee** | **Fee Increase/Decrease** |
| 1 | Submission of sequence listings of 300MB to 800MB | New fee | $1,000 (large entity)  $500 (small entity)  $250 (micro entity) | New fee |
| 1 | Submission of sequence listings of more than 800MB | New fee | $10,000 (large entity)  $5,000 (small entity)  $2,500 (micro entity) | New fee |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter | New fee | $300 (large entity)  $150 (small entity)  $75 (micro entity) | New fee |

**Table 3: Increases in Hourly Burden Respondents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IC #** | **Item** | **Current Annual Responses** | **Proposed Annual Responses** | **Increase in Responses** |
| 1 | Submissions of sequence listings of 300MB to 800 MB (large entity) | 0 | 6 | 6 |
| 1 | Submissions of sequence listings of 300MB to 800 MB (small entity) | 0 | 2 | 2 |
| 1 | Submissions of sequence listings of 300MB to 800 MB (micro entity) | 0 | 1 | 1 |
| 1 | Submissions of sequence listings of more than 800 MB (large entity) | 0 | 2 | 2 |
| 1 | Submissions of sequence listings of more than 800 MB (small entity) | 0 | 1 | 1 |
| 1 | Submissions of sequence listings of more than 800 MB (micro entity) | 0 | 1 | 1 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (large entity) | 0 | 247 | 247 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (small entity) | 0 | 50 | 50 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (micro entity) | 0 | 5 | 5 |
|  | **Totals** | **0** | **315** | **315** |

**Table 4: Increases in Non-Hourly Costs (Fees)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IC #** | **Item** | **Current Total Burden ($)** | **Proposed Total Cost ($)** | **Total Cost Increase** |
| 1 | Submissions of sequence listings of 300MB to 800 MB (large entity) | 0 | $6,000.00 | $6,000.00 |
| 1 | Submissions of sequence listings of 300MB to 800 MB (small entity) | 0 | $1,000.00 | $1,000.00 |
| 1 | Submissions of sequence listings of 300MB to 800 MB (micro entity) | 0 | $250.00 | $250.00 |
| 1 | Submissions of sequence listings of more than 800 MB (large entity) | 0 | $20,000.00 | $20,000.00 |
| 1 | Submissions of sequence listings of more than 800 MB (small entity) | 0 | $5,000.00 | $5,000.00 |
| 1 | Submissions of sequence listings of more than 800 MB (micro entity) | 0 | $2,500.00 | $2,500.00 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (large entity) | 0 | $74,100.00 | $74,100.00 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (small entity) | 0 | $7,500.00 | $7,500.00 |
| 1 | Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (micro entity) | 0 | $375.00 | $375.00 |
|  | **Totals** | **0** | **$116,725.00** | **$116,725.00** |

Summary of Changes

The addition of 3 fees (broken down into large entities, small entities, and micro entities), 315 respondents, and $116,725 in non-hourly costs to collection 0651-0012 account following the rulemaking action NPRM 0651-AD02.

Changes in Burden

|  |  |  |  |
| --- | --- | --- | --- |
| **Burden Type** | **Currently Approved** | **Proposed Changes** | **New Estimates** |
| Respondents | 27,200 | 315 | 27,515 |
| Non-hour Costs | $1,815,457.50 | $116,725.00 | $1,932,182.50 |

The 0651-0024 revised total burden is as follows:

* 27,515 respondents
* $1,932,182.50 in annual (non-hour) costs