



THINK FORWARD

New USPTO Mega-Sequence Listing Fees

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On November 14, 2017, the United States Patent and Trademark Office (USPTO) published a rule on "Setting and Adjusting Patent Fees During Fiscal Year 2017." (82 FR 52780) This rule includes fee adjustments that take effect on January 16, 2018. The USPTO designated some adjustments as "new and significant fees." One of these new additions is a fee for mega-sequence listings. This change will be implemented through amendment of 37 C.F.R. § 1.21.

37 C.F.R. § 1.821 regulates nucleotide and amino acid sequence listings furnished to the USPTO. There is currently no fee for submitting a large sequence listing unless the sequence listing is submitted as a PDF and implicates the application size fee. Generally, sequence listings submitted as a text file via EFS-Web are excluded when determining the application size fee.

The current size limit for sequence listing text files via EFS-Web is 100 megabytes (MB). Applicants may submit larger sequence listings on compact disc. The new fees for mega-sequence listing filings are for sequence listings of 300 MB and up. The fee for submission of sequence listings of 300 MB to 800 MB is \$1,000 (small entity \$500 and micro entity \$250). The fee for submission of sequence listings of more than 800 MB is \$10,000 (small entity \$5,000 and micro entity \$2,500).

As discussed in the Manual of Patent Examining Procedure (MPEP) § 2422.01, the requirement for compliance with 37 C.F.R. § 1.821 encompasses "disclosures of nucleotide and/or amino acid sequences," even non-claimed sequences. If prior art sequences are merely referred to by name and a publication or accession reference, these sequences need not be included in the sequence listing unless the sequence is "essential material" according to MPEP § 608.01(p) ("Completeness of Specification"). If, however, an application discloses a sequence as a string of nucleotide bases or amino acids, it is necessary to include the sequence in a sequence listing regardless of prior art status.

The USPTO is now implementing mega-sequence listing fees to encourage patent applicants to exclude non-essential sequence data from sequence listings. Applications with claims to the manipulation of sequence data rather than claims directed to the listed sequences themselves do not often require a mega-sequence listing, and the USPTO's fee schedule now discourages inclusion of this type of data in sequence listings.

The USPTO explains that the level of effort associated with mega-sequence listings is significant due to the need for extra handling and storage. The additional fees are expected to reduce the strain on the institution's resources. To avoid paying the fee for mega-sequence listings, applicants should review their applications for unclaimed sequences and determine whether some sequences may be identified by reference. The selection of particular sequences, however, should be carefully considered since sequences excluded from a listing may possibly be considered prior art or non-essential during examination of the application's claims.

Further information is available at: <https://www.federalregister.gov/documents/2017/11/14/2017-24390/setting-and-adjusting-patent-fees-during-fiscal-year-2017>

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