

**DEPARTMENT OF COMMERCE****Patent and Trademark Office****Submission for OMB Review; Comment Request; Patent Term Extension**

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* United States Patent and Trademark Office, Commerce.

*Title:* Patent Term Extension.

*OMB Control Number:* 0651-0020.

*Form Number(s):* N/A.

*Type of Request:* Renewal.

*Number of Respondents:* 1,340.

*Average Hours per Response:* 1 hour to 25 hours, depending upon the instrument used.

*Burden Hours:* 6,187 hours.

*Cost Burden:* \$351,505.08.

*Needs and Uses:* The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. 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. The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710-1.791. 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 administers 35 U.S.C. 154 through 37 CFR 1.701-1.705.

The public uses this information collection to file requests related to patent term extensions and reconsideration or reinstatement of patent term adjustments. 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.

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

*Frequency:* On occasion.

*Respondent's Obligation:* Required to obtain or retain benefits.

*OMB Desk Officer:* Kimberly R.

Keravuori, email: [Kimberly\\_R\\_Keravuori@omb.eop.gov](mailto:Kimberly_R_Keravuori@omb.eop.gov).

Once submitted, the request will be publicly available in electronic format through [reginfo.gov](http://reginfo.gov). Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- *Email:* [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include "0651-0020 copy request" in the subject line of the message.

- *Mail:* Marcie Lovett, Records Management Division Director, OCIO, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

Written comments and recommendations for the proposed information collection should be sent on or before November 28, 2016 to Kimberly R. Keravuori, OMB Desk Officer, via email to [Kimberly\\_R\\_Keravuori@omb.eop.gov](mailto:Kimberly_R_Keravuori@omb.eop.gov), or by fax to 202-395-5167, marked to the attention of Kimberly R. Keravuori.

Dated: October 20, 2016.

**Marcie Lovett,**

*Records Management Division Director, OCIO, United States Patent and Trademark Office.*

[FR Doc. 2016-25951 Filed 10-26-16; 8:45 am]

**BILLING CODE 3510-16-P**

**DEPARTMENT OF COMMERCE****Patent and Trademark Office**

[Docket No.: PTO-P-2016-0039]

**Standard ST.26—Request for Comments on the Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language)**

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Request for comments.

**SUMMARY:** Patent applications that contain disclosures of nucleotide and/or amino acid sequences must contain sequence information in a separate part of the disclosure in a specified manner. The United States Patent and Trademark Office (Office) is seeking additional comments to obtain views of the public on the continuing international effort to revise the World Intellectual Property Organization (WIPO) standard for the presentation of nucleotide and/or amino acid sequences and the consequent changes to the United States rules of practice. The revised standard will be known as WIPO Standard ST.26. An interim version of WIPO Standard ST.26 was adopted in March 2016 by the Committee on WIPO Standards (CWS), but has not been implemented pending further consideration by the CWS. Since the adoption of the interim version, efforts have been undertaken to finalize WIPO Standard ST.26 and to improve its effectiveness once implemented. One aspect of that continuing effort is a proposed guidance document annex, which will include a variety of sequence disclosure examples, to ensure understanding and uniform application of standard requirements. Comments may be offered on any aspect of this effort, and in particular, (a) the comprehensiveness and clarity of WIPO Standard ST.26 and the proposed guidance document annex, and (b) the proposed authoring/validation tool for creation of a sequence listing in XML.

**DATES:** Written comments must be received on or before December 27, 2016 to ensure consideration. No public hearing will be held.

**ADDRESSES:** Comments concerning this notice should be sent by electronic mail message over the Internet addressed to [seq\\_listing\\_xml@uspto.gov](mailto:seq_listing_xml@uspto.gov). Comments may also be submitted by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of Susan C. Wolski, Office of International Patent Legal Administration, Office of the Deputy Commissioner for International Patent Cooperation. Although comments may be submitted by mail, the Office prefers to receive comments via the Internet.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available via the Internet (<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not

desire to make public, such as an address or phone number, should not be included in the comments.

**FOR FURTHER INFORMATION CONTACT:** Susan C. Wolski, Office of International Patent Legal Administration, Office of the Deputy Commissioner for International Patent Cooperation, by telephone at (571) 272-3304, or by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, marked to the attention of Susan C. Wolski.

#### **SUPPLEMENTARY INFORMATION:**

##### **1. Background Information**

Patent applicants are currently required to submit biological sequence data in a standardized electronic format in accordance with WIPO Standard ST.25, both within the framework of the Patent Cooperation Treaty (PCT) (Annex C of the Administrative Instructions) and under most national and regional provisions. The Rules of Patent Practice in the United States (37 CFR 1.821–1.825) were amended to implement WIPO Standard ST.25 in July of 1998. See *Requirements for Patent Applications Containing Nucleotide Sequences and/or Amino Acid Disclosures*, 63 FR 29620 (June 1, 1998), 1121 *Off. Gaz. Pat. Office* 82 (June 23, 1998).

WIPO Standard ST.25, which became effective in 1998 and has not been revised since that time, requires a flat file structure of numeric identifiers using a limited set of character codes. In October 2010, the CWS established a Task Force, designating the European Patent Organization as the lead, to draft a revised standard (WIPO Standard ST.26) for the filing of nucleotide and/or amino acid sequence listings in XML format. The Office issued a first request for comments on WIPO Standard ST.26 as drafted by the Task Force (see *Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26)*, 77 FR 28541 (May 15, 2012), 1379 *Off. Gaz. Pat. Office* 106 (June 12, 2012)), following which the draft was revised in response to comments received. In March 2016, the reconvened fourth session of the CWS adopted an interim version of WIPO Standard ST.26, which had been initially considered at the fourth session of the CWS in May 2014. The interim version of WIPO Standard ST.26 contains an editorial note requesting that implementation be postponed until the recommendation for the transition from WIPO Standard ST.25 to WIPO Standard ST.26 is agreed on by the CWS

at its next session to be held in 2017. Meanwhile, WIPO Standard ST.25 should continue to be used. The adopted interim version of WIPO Standard ST.26 is composed of six documents, namely, the main body of the standard, a first annex setting forth the controlled vocabulary for use with the sequence part of the standard, a second annex setting forth the Document Type Definition (DTD) for the standard, a third annex containing a sequence listing specimen, a fourth annex setting forth the character subset from the Unicode Basic Latin Code Table, and a fifth annex setting forth additional data exchange requirements for patent offices, and can be found here: <http://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf>. Since the adoption of the interim version, the main body, the controlled vocabulary, and the DTD have been further revised and updated. In addition, a sixth annex has been proposed; it would contain a guidance document that aims to ensure that all applicants and Intellectual Property Offices (IPOs) understand and agree on the requirements for inclusion and representation of sequence disclosures. In all, seven rounds of discussion have been completed since March 2011, and currently, the eighth round of discussion of the documents is ongoing.

##### **2. Request for Comments**

The Office, leading the negotiations for the United States, is seeking public comment on WIPO Standard ST.26, as revised subsequent to the adoption of the interim version. To that end, the current revisions of the main body of the standard and its five annexes, as well as the newly proposed sixth annex, are available via the Office's Web site at <http://www.uspto.gov/patent/laws-and-regulations/comments-public/2016-comments-standard-st26-presentation-nucleotide-and>.

Written comments may be offered on any aspect of WIPO Standard ST.26, its annexes, or the proposed authoring/validation tool. Comments are specifically requested on the following issues:

###### *(a) WIPO Standard ST.26 Main Body*

Since the first request for comments, the main body of WIPO Standard ST.26 has been revised, *inter alia*, to define a "nucleotide" to include nucleotide analogues and to provide further guidance on representation of nucleotide analogue sequences and variant sequences that have been disclosed as a single sequence with enumerated alternative variant residues at one or more positions.

The Office invites comments on whether the main body of WIPO Standard ST.26 is sufficiently comprehensive and clear, and in particular welcomes suggestions to add details or clarify the language as appropriate.

###### *(b) Guidance Document*

One goal of the development of a WIPO Standard for sequence listings is to allow patent applicants to draw up a single sequence listing in a patent application that would be acceptable for the purposes of both international and national or regional prosecution worldwide. Any new standard should represent the maximum requirements for any sequence listing submission. The purpose of the guidance document is to ensure that all applicants and IPOs understand and agree on the requirements for inclusion and representation of sequence disclosures, such that this purpose is realized.

The guidance document is composed of an introduction, examples, and a sequence listing in XML demonstrating representation of the exemplified sequences. The introduction defines terminology used in the document and discusses the questions raised for each example, namely, whether inclusion is required for a particular disclosed sequence, if inclusion of the sequence is permitted when it is not required, and the appropriate means of representation of sequences included in a sequence listing. Examples were chosen to illustrate various paragraphs of the main body and include 22 involving nucleotide sequences and 19 involving amino acid sequences. It is envisioned that the guidance document would be updated as necessary to include further examples to keep pace with technological advances.

The Office invites comments on whether the guidance document is sufficiently comprehensive and clear, and in particular welcomes suggestions to add details or further examples as appropriate.

###### *(c) Authoring and Validation Tool*

Availability of an authoring tool in advance of the WIPO Standard ST.26 effective date is key to a successful transition from WIPO Standard ST.25. As envisioned, the authoring tool should be capable of intake of a sequence listing in WIPO Standard ST.25 format, and with additional input from applicant, create a sequence listing in WIPO Standard ST.26 format. Unfortunately, direct conversion from one standard to the other is not possible, due to numerous differences between the two standards, including *inter alia*,

the types of required sequences, representation and annotation of the sequences, and sequence data structure.

The authoring tool should also prompt entry of all required data, prevent entry of sequences having fewer than ten specifically defined nucleotides or fewer than four specifically defined amino acids, inform as to the possibility of optional annotations, and allow use of only acceptable values or formats where applicable, thereby enhancing submission quality. A sequence listing in WIPO Standard ST.26 XML format is not as easily human-readable as its ST.25 counterpart; therefore, the tool should also provide a means for easily viewing both the in-progress and completed sequence listing.

Because the authoring tool is expected to prompt entry of all required data and to allow use of only acceptable values or formats where applicable, a certain level of validation occurs as data is entered. The tool is further expected to include a separate validation function for use by both applicants and IPOs.

WIPO Standard ST.25 provides for a single numeric identifier <223> per sequence to contain "free text" to describe sequence characteristics using non-language neutral vocabulary. Such "free text" is required to be repeated in the main part of the application description in the language thereof in a specific recommended section entitled "Sequence Listing Free Text." Such repetition ensures that any "free text" will be translated together with the application description, precluding the need for separate translation of the sequence listing itself. In contrast, WIPO Standard ST.26 allows use of "free text" as the value for multiple different annotation qualifiers per sequence, and due to the absence of procedural requirements, repetition in the application is not required, although such a requirement under the PCT and by various IPOs is possible. In WIPO Standard ST.26, "free text" is limited to a few short terms indispensable for understanding a characteristic of a sequence, is preferably in the English language, and as part of the sequence data part of the sequence listing, must not exceed 1000 characters composed of printable characters from the Unicode Basic Latin code table. It is expected that most inventors providing sequence information are capable of providing "free text" in the English language.

The Office invites comments on any aspect of the authoring tool, and in particular welcomes feedback on whether it is deemed necessary for the authoring tool to include a mechanism for automatic identification and

extraction of any "free text" from sequence annotations to facilitate inclusion in the application description.

Dated: October 21, 2016.

**Michelle K. Lee,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2016-25968 Filed 10-26-16; 8:45 am]

**BILLING CODE 3510-16-P**

## DEPARTMENT OF EDUCATION

[Docket No.: ED-2016-ICCD-0116]

### Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Satisfactory Academic Progress Policy

**AGENCY:** Department of Education (ED), Federal Student Aid (FSA)

**ACTION:** Notice

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2016.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2016-ICCD-0116. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E-347, Washington, DC 20202-4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of

information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* Student Assistance General Provisions—Satisfactory Academic Progress Policy.

*OMB Control Number:* 1845-0108.

*Type of Review:* A revision of an existing information collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments; Individuals or Households; Private Sector.

*Total Estimated Number of Annual Responses:* 33,543,341.

*Total Estimated Number of Annual Burden Hours:* 1,470,256.

*Abstract:* The Department of Education (the Department) is making this request is for an extension of the current approval of the policies and procedures for determining satisfactory academic progress (SAP) as required in Section 484 of the Higher Education Act of 1965, as amended (HEA). These regulations identify the policies and procedures to ensure that students are making satisfactory academic progress in their program at a pace and a level to receive or continue to receive Title IV, HEA program funds. If there is lapse in progress, the policy must identify how the student will be notified and what steps are available to a student not making satisfactory academic progress toward the completion of their program, and under what conditions a student who is not making satisfactory academic progress may continue to receive Title IV, HEA program funds.