

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## **PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS**

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0390 to read as follows:

### **§ 165.T08–0390 Safety Zone; La Quinta and Corpus Christi Shipping Channel, Ingleside, TX.**

(a) *Location.* The following area is a safety zone: all navigable waters of the La Quinta Channel between gated pair lights 11 and 12 to the Sea buoy. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative.

(b) *Enforcement period.* This section will be enforced from 11 p.m. on May 27, 2023 through 11 a.m. on May 28, 2023.

(c) *Regulations.* (1) According to the general regulations in § 165.23 of this part, entry into this temporary safety zone is prohibited unless authorized by the COTP or a designated representative. They may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450.

(2) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate.

Dated: May 22, 2023.

**J.B. Gunning,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.*

[FR Doc. 2023–11387 Filed 5–24–23; 4:15 pm]

**BILLING CODE 9110–04–P**

## **DEPARTMENT OF COMMERCE**

### **Patent and Trademark Office**

#### **37 CFR Part 1**

[Docket No. PTO–P–2023–0013]

**RIN 0651–AD69**

#### **Adoption of Updated WIPO Standard ST.26; Revision to Incorporation by Reference**

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

**ACTION:** Final rule.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) is adopting the recently revised World Intellectual Property Organization (WIPO) Standard ST.26, version 1.6, approved November 25, 2022, for incorporation by reference into its regulations addressing application disclosures containing nucleotide and/or amino acid sequences. The USPTO is also correcting a grammatical oversight in one of its sequence regulations. The USPTO first amended its rules in 2022 to incorporate by reference certain provisions of WIPO Standard ST.26. In addition to simplifying the process for applicants filing in multiple countries, the ST.26 requirement to submit a single sequence listing in eXtensible Markup Language (XML) format provides better preservation, accessibility, and sorting of the submitted sequence data for the public. Among other improvements, the new version of ST.26 clarifies requirements, improves descriptions, and corrects editorial mistakes.

**DATES:** This final rule is effective on July 1, 2023. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of July 1, 2023.

**FOR FURTHER INFORMATION CONTACT:** Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at [Mary.Till@uspto.gov](mailto:Mary.Till@uspto.gov) or 571–272–7755; or Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at [Ali.Salimi@uspto.gov](mailto:Ali.Salimi@uspto.gov) or 571–272–0909.

**SUPPLEMENTARY INFORMATION:** The “WIPO Handbook on Intellectual Property Information and Documentation” (formerly the “WIPO Handbook on Industrial Property Information and Documentation”) sets forth standards for the presentation of data in many contexts. One such standard is WIPO Standard ST.26, which is titled “RECOMMENDED

STANDARD FOR THE PRESENTATION OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS USING XML (EXTENSIBLE MARKUP LANGUAGE).” WIPO Standard ST.26 defines the disclosures of nucleotide and/or amino acid sequences in patent applications that must be presented in a sequence listing in XML format in the manner specified in the standard.

In a rulemaking published May 20, 2022, at 87 FR 30806, the USPTO created new rules 37 CFR 1.831–1.839 that incorporate by reference WIPO Standard ST.26. 37 CFR 1.839(b)(1) specifically identifies the version of WIPO Standard ST.26 that has been incorporated by reference as “version 1.5, approved November 5, 2021.” On November 25, 2022, WIPO adopted a new version (version 1.6) of WIPO Standard ST.26. As a result, the USPTO is updating 37 CFR 1.839(b)(1) to reflect the new version.

WIPO provides free online public access to view copies of its standards. WIPO standards that are incorporated into Federal regulations are available to the public for free viewing on WIPO’s website at [https://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01\\_v1\\_6.pdf](https://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01_v1_6.pdf). In addition to the free online availability of this standard on WIPO’s website, WIPO Standard ST.26 is available on the USPTO’s Sequence Listing Resource Center at <https://www.uspto.gov/patents/apply/sequence-listing-resource-center>.

WIPO Standard ST.26 is composed of eight documents, namely, the main body of the standard, a first annex (Annex I) setting forth the controlled vocabulary for use with the main body, a second annex (Annex II) setting forth the Document Type Definition (DTD) for the Sequence Listing, a third annex (Annex III) containing a sequence listing specimen (XML file), a fourth annex (Annex IV) setting forth the character subset from the Unicode Basic Latin Code Table, a fifth annex (Annex V) setting forth additional data exchange requirements for IPOs, a sixth annex (Annex VI) containing a guidance document with illustrated examples, and a seventh annex (Annex VII) setting forth recommendations for the transformation of a sequence listing from WIPO Standard ST.25 format to WIPO Standard ST.26 format, including guidance on how to avoid adding or deleting subject matter.

Revisions to WIPO Standard ST.26 under the newly adopted version affect the main body, Annex I, Annex II, Annex VI, and Annex VII. The changes to the main body serve to clarify requirements, improve descriptions (for example, by better defining the value

needed for an application number), and correct editorial mistakes. Similarly, the changes to Annex I, Annex II and Annex VII clarify the format of values for identifiers that are part of the “Sequence Listing XML,” revise grammar, and clarify values that are language-dependent. Annex VI includes three new examples of the manner in which (1) a circular nucleotide sequence is exemplified, (2) a post-translationally modified amino acid is exemplified, and (3) representation of a single sequence with enumerated alternative amino acids that may be modified amino acids is exemplified. Throughout the main body of WIPO Standard ST.26, reference to “international, national or regional procedures” have been updated to reflect that order for consistency. Furthermore, all instances of “industrial property” in the main body of WIPO Standard ST.26 have been updated to “intellectual property.” Thus, the changes in newly adopted version 1.6 of WIPO Standard ST.26 are ministerial changes that will not have a meaningful substantive impact on disclosing parties.

Additionally, the USPTO revises 37 CFR 1.831(a) to correct a grammatical oversight. 37 CFR 1.831(d) corresponds to WIPO Standard ST.26, paragraph 3(c)(i) and (ii), and recites “enumeration of its residues,” but 37 CFR 1.831(a), as implemented in the May 2022 rulemaking, recited “enumeration of their residues.” This grammatical error was an oversight, and the changes in § 1.831(a) to replace “enumeration of their residues” with “enumeration of its residues” do not impact compliance with how an amino acid and/or nucleotide sequence(s), which is enumerated by its residues, must be shown in the “Sequence Listing XML.”

### Discussion of Specific Rules

**Section 1.831:** Section 1.831(a) is amended to replace “Patent applications disclosing nucleotide and/or amino acid sequences by enumeration of their residues . . .” with “Patent applications disclosing a nucleotide and/or amino acid sequence(s) by enumeration of its residues . . .” for consistency with § 1.831(d) and WIPO Standard ST.26, paragraph 3(c)(i) and (ii), to which § 1.831(d) corresponds. A subsequent iteration of “nucleotide and/or amino acid sequences” in § 1.831(a) is revised to “nucleotide and/or amino acid sequence(s)” for consistency.

**Section 1.839:** Section 1.839(b)(1) is amended to provide an updated citation to the WIPO Standard ST.26 that is being incorporated by reference. Additionally, § 1.839(b)(1) is revised to reflect an update to the name of the

WIPO handbook. Specifically, the “WIPO Handbook on Industrial Property Information and Documentation” is now the “WIPO Handbook on Intellectual Property Information and Documentation.”

### Rulemaking Considerations

**A. Administrative Procedure Act:** The changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. See *Bachow Commc’ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (changes to procedural rules are not subject to notice and comment review under the Administrative Procedure Act (APA)); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 349 (4th Cir. 2001) (rules for handling appeals are procedural where they do not change the substantive standard for reviewing claims); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Substantive rules “effect a change in existing law or policy or which affect individual rights and obligations,” whereas interpretative rules “clarify or explain existing law or regulation and are exempt from notice and comment” review under the APA.).

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. See *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(A))).

In addition, the Office finds good cause pursuant to the authority at 5 U.S.C. 553(b)(B) to dispense with prior notice and opportunity for public comment because such procedures are unnecessary in this instance. The changes in this rulemaking merely update the regulations to incorporate by reference version 1.6 of WIPO Standard ST.26, which was adopted on November 25, 2022, by the WIPO Committee on Standards, and to make a correction to the regulations at 37 CFR 1.831(a) to correct a grammatical oversight in a definition. These revisions are largely procedural in nature, and do not impose any additional requirements or fees on applicants. Thus, the USPTO implements this final rule without prior notice and opportunity for comment.

**B. Regulatory Flexibility Act:** As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a Regulatory Flexibility Act analysis nor a

certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. See 5 U.S.C. 603.

**C. Executive Order 12866 (Regulatory Planning and Review):** This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

**D. Executive Order 13563 (Improving Regulation and Regulatory Review):** The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, to the extent feasible and applicable, the USPTO has: (1) reasonably determined that the benefits of the rule justify its costs; (2) tailored the rule to impose the least burden on society consistent with obtaining the agency’s regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens while maintaining flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

**E. Executive Order 13132 (Federalism):** This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

**F. Executive Order 13175 (Tribal Consultation):** This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

**G. Executive Order 13211 (Energy Effects):** This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

**H. Executive Order 12988 (Civil Justice Reform):** This rulemaking meets

applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

*I. Executive Order 13045 (Protection of Children):* This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

*J. Executive Order 12630 (Taking of Private Property):* This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

*K. Congressional Review Act:* Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

*L. Unfunded Mandates Reform Act of 1995:* The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

*M. National Environmental Policy Act of 1969:* This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

*N. National Technology Transfer and Advancement Act of 1995:* The requirements of section 12(d) of the National Technology Transfer and

Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

*O. Paperwork Reduction Act of 1995:* This final rule does not impact information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information has a currently valid OMB control number.

*P. E-Government Act Compliance:* The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Incorporation by reference, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble and under the authority contained in 35 U.S.C. 2, as amended, the USPTO amends 37 CFR part 1 as follows:

#### PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for part 1 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. In § 1.831, revise paragraph (a) to read as follows:

##### **§ 1.831 Requirements for patent applications filed on or after July 1, 2022, having nucleotide and/or amino acid sequence disclosures.**

(a) Patent applications disclosing a nucleotide and/or amino acid sequence(s) by enumeration of its residues, as defined in paragraph (b) of this section, must contain, as a separate part of the disclosure, a computer readable Sequence Listing in XML format (a “Sequence Listing XML”). Disclosed nucleotide or amino acid sequences that do not meet the definition in paragraph (b) of this section must not be included in the “Sequence Listing XML.” The

“Sequence Listing XML” contains the information of the nucleotide and/or amino acid sequence(s) disclosed in the patent application using the symbols and format in accordance with the requirements of §§ 1.832 through 1.834.

\* \* \* \* \*

■ 3. In § 1.839, revise paragraph (b)(1) to read as follows:

##### **§ 1.839 Incorporation by reference.**

\* \* \* \* \*

(b) \* \* \*

(1) WIPO Standard ST.26. WIPO Handbook on Intellectual Property Information and Documentation, Standard ST.26: Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language) including Annexes I–VII, version 1.6, approved November 25, 2022; IBR approved for §§ 1.831 through 1.834.

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**Katherine K. Vidal,**

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

[FR Doc. 2023–11365 Filed 5–25–23; 8:45 am]

**BILLING CODE 3510–16–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R10–OAR–2022–0753, FRL–10190–02–R10]

#### Air Plan Approval; ID; State Board Composition

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving a revision to the Idaho State Implementation Plan (SIP) submitted on August 9, 2022. The revision was submitted to meet the state board composition requirements of the Clean Air Act.

**DATES:** This final rule is effective June 26, 2023.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2022–0753. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as