



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2024-0018]

RIN 0651-AD80

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) is adopting version 1.7 of World Intellectual Property Organization (WIPO) Standard ST.26, which was approved December 8, 2023, for incorporation by reference into the USPTO's regulations addressing application disclosures containing nucleotide and/or amino acid sequences. Among other enhancements, version 1.7 of ST.26 provides technical terminology consistency and improves descriptions.

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.

DATES: This final rule is effective on July 1, 2024. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of July 1, 2024.

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, at 571-272-0909; or Raul Tamayo, Senior Legal Advisor, at 571-272-7728, both of the Office of Patent Legal Administration; or to PatentPractice@uspto.gov.

SUPPLEMENTARY INFORMATION: The “WIPO Handbook on Intellectual 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 final rule 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. In a final rule published May 26, 2023, 88 FR 34089, the USPTO updated 37 CFR 1.839(b)(1) to reflect version 1.6 of WIPO Standard ST.26. On December 8, 2023, WIPO adopted a new version (version 1.7) of WIPO Standard ST.26. As a result, the USPTO is again updating 37 CFR 1.839(b)(1).

WIPO provides free online public access to view copies of its standards, including version 1.7 of WIPO Standard ST.26, on its website at www.wipo.int/standards/en/part_03_standards.html. WIPO Standard ST.26 is also

available on the USPTO's Sequence Listing Resource Center at www.uspto.gov/patents/apply/sequence-listing-resource-center.

WIPO Standard ST.26 is comprised of eight documents: the main body of the standard, a first annex (Annex I) setting forth the controlled vocabulary for use with the main body, Annex II setting forth the Document Type Definition (DTD) for the Sequence Listing, Annex III containing a sequence listing specimen (XML file), Annex IV setting forth the character subset from the Unicode Basic Latin Code Table, Annex V setting forth additional data exchange requirements for IPOs, Annex VI containing a guidance document with illustrated examples, and 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 version 1.7 affect the main body and Annex VI. The changes to the main body improve the consistency of technical terminology. In paragraph 3(f), all instances of "3'-monophosphate" were changed to "5'-monophosphate" to be consistent with paragraph 3(g) and standard nucleotide naming conventions.

Similarly, the changes to Annex VI improve consistency and clarity of terminology and correct technical errors. All instances of "3'-monophosphate" were changed to "5'-monophosphate" to be consistent with the changes made to the main body. In Examples 14-1 and 30-2, scientific and grammatical corrections were made to clarify the example disclosures. In addition, Annex VI includes two new examples that demonstrate how sequences with inverted nucleotides should be included in a sequence listing. Finally, the "Example Index" in Annex VI was simplified by removing the "Cross-referenced examples."

Thus, the changes in version 1.7 of WIPO Standard ST.26 are ministerial changes that will not have a meaningful substantive impact on disclosing parties.

Discussion of Specific Rules

Section 1.839: Section 1.839(b)(1) is amended to provide an updated citation to version 1.7 of WIPO Standard ST.26 that is being incorporated by reference.

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 USPTO 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 1.7 of WIPO Standard ST.26, which was adopted on December 8, 2023, by the WIPO Committee on Standards. 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 (September 30, 1993), as amended by Executive Order 14094 (April 6, 2023).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (January 18, 2011). Specifically, and as discussed above, the USPTO has, to the extent feasible and applicable: (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 pertains strictly to federal agency procedures and does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 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 (November 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 (February 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 (April 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 (March 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 § 1.839, 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 1.7, approved December 8, 2023; IBR approved for §§ 1.831 through 1.834.

* * * * *

Katherine K. Vidal,

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

[FR Doc. 2024-09618 Filed: 5/2/2024 8:45 am; Publication Date: 5/3/2024]