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REPORT ON TASK NO. 44 BY THE SEQUENCE LISTINGS TASK FORCE

Document prepared by the Sequence Listings Task Force Leader

SUMMARY

1. The document provides a summary of the progress made by the Sequence Listings Task Force since the last session of the Committee on WIPO Standards (CWS). There is no revision planned for WIPO Standard ST.26 at this session.

BACKGROUND

2. The Sequence Listings Task Force was created by the CWS, at its first session (October 25 to 29, 2010), to perform Task No. 44, namely to prepare a recommendation on the presentation of nucleotide and amino acid sequence listings based on eXtensible Markup Language (XML) for adoption as a WIPO standard. The EPO was assigned the role of Task Force Leader. The Task Force was also requested to liaise with the appropriate PCT body regarding the possible impact of such a Standard on Annex C to the Administrative Instructions under the PCT. (See paragraph 29 of document CWS/1/10)

3. At its reconvened fourth session, WIPO Standard ST.26 was adopted by the CWS in 2016. In October 2021, at the fifty-third session of the PCT Assembly, the amendments to the PCT Regulations to implement WIPO Standard ST.26 in the PCT system were adopted. The WIPO General Assembly approved to delay the "big-bang" implementation date of WIPO Standard ST.26 to July 1, 2022, at national, regional and international levels (see document WO/GA/54/14 and paragraphs 178 to 183 of document WO/GA/54/15).

4. At the eleventh session of the CWS in 2023, the CWS approved a revision of the description of Task No. 44, which reads now as follows:

"*Support the International Bureau by testing new releases based on available resources and providing user feedback on the WIPO Sequence Suite; and prepare necessary revisions of WIPO Standard ST.26"*

5. Since the Standard was first adopted in 2016, there have been several updates resulting in versions 1.1, 1.2, 1.3, 1.4, 1.5 and 1.6. Most recently at the eleventh session, held in December 2023, the CWS adopted version 1.7, adding new examples to Annex VI of WIPO ST.26 and the Appendix to Annex VI.

PROGRESS REPORT

6. Since the last session of the CWS, the Task Force met twice online, on February 27 and on July 18, 2024, and discussed the status of the WIPO Sequence Suite performance improvement project and potential revisions to WIPO Standard ST.26. Regarding the proposed revisions, the Task Force has discussed:

- a proposal to require a subset of nucleotide analogs and peptide analogs to be represented by the corresponding unmodified residue symbol, which was presented by the United States Patent and Trademark Office (USPTO);

- a proposal to lift the minimum sequence length requirement, which was presented by the European Patent Office (EPO); and

- some editorial improvements.

7. The current version of WIPO Standard ST.26 allows for a sequence consisting of nucleotide analog residues or peptide analog residues to be represented entirely as non-specifically defined residues (i.e., "n" or "X"), with the effect that such sequences are not required to be included in a sequence listing. The USPTO proposal to require that certain nucleotide analog residues and peptide analog residues be represented by the symbol for the corresponding unmodified residue will make them specifically defined. As a result, some sequences that were optional to include in a sequence listing under versions 1.5, 1.6 or 1.7 of WIPO ST.26, would become mandatory to include in a sequence listing under the proposed WIPO ST.26 version 2.0.

8. The Task Force discussed this proposal concerning the representation of nucleotide and peptide analogs at its meeting on 18 July 2024. Task Force Members generally acknowledged the benefits of this proposal for the improvement of search accuracy. However, they also noted that it would result in additional effort being required by examiners for the manual review of compliance with the new requirement.

9. For the implementation of WIPO Standard ST.26 version 2.0, the Task Force proposed that all patent applications filed on or after the entry into force date of version 2.0 must comply with this new version. Any sequence listing furnished in respect of a patent application filed prior to the entry into force date of version 2.0 should still comply with one of the earlier versions: versions 1.5, 1.6 or 1.7. For continuing applications filed on or after the entry into force of the new version 2.0 that have a parent application filed when WIPO ST.26 version 1.5, 1.6 or 1.7 was in effect, there are two alternative transition regimes for implementation:

> Option 1: an application filed on or after the entry into force date of version 2.0 that is a continuing application of an application filed under an earlier version of WIPO Standard ST.26 will be evaluated under version 1.7 rules; i.e., modified residues should be represented in a sequence as the corresponding unmodified residue whenever possible, but this representation is not a requirement; or

Option 2: an application filed on or after the entry into force date of version 2.0 that is a continuing application of an application filed under an earlier version of WIPO Standard ST.26 will be evaluated under version 2.0 rules; i.e., it is mandatory to represent certain modified residues using the symbol of the corresponding unmodified residue in a sequence.

10. Members of the Task Force agreed that this proposal would result in a substantive revision to WIPO Standard ST.26 and that more time would be needed to consider the impact of the proposed amendment and the two proposed transition regimes.

11. The EPO proposal concerns the lifting of the minimum sequence length requirement, which restricts the inclusion of short sequences (nucleotide sequences less than 10 specifically defined residues and amino acid sequences less than 4 specifically defined amino acids), on the grounds that these sequences are important to search for specific domains such as antibodies, defined by short Complementarity Determining Regions (CDRs), therapeutic nucleic acids, aptamers and peptides. The European Bioinformatics Institute (EBI) confirmed with the EPO that they do not reject small sequences. As the members of the International Nucleotide Sequence Database Collaboration (INSDC) exchange data daily, the potential inclusion of small sequences in the public databases merits further investigation by the Task Force. This proposal would also likely result in a substantive revision to the Standard.

12. The Task Force agreed to collect the arguments and counterarguments for the short sequence proposal in order to ensure that all Task Force members understand the issues and can discuss them. The Task Force also agreed to collect feedback on the proposal from the users of WIPO Standard ST.26 through a formal survey. Therefore, the Task Force plans to prepare a survey questionnaire which should be addressed to patent applicants, IPOs and any other interested parties. The Task Force proposes to discuss the survey scope and process, and potential questions for the survey questionnaire at the present session.

12. As the WIPO ST.26 is considered stable at this moment, the Task Force concluded that more discussions and further consultations are required before the submission of these two proposals for revision to the CWS for consideration and approval. Pending such a substantive update, the Task Force selected to not propose a new minor revision of WIPO Standard ST.26 for consideration and approval, which would be limited to editorial improvements only.

WORK PLAN

13. The following items are considered a priority in the upcoming year for the Sequence Listings Task Force:

(a) Preparation of the formal survey questionnaire regarding the EPO proposal, as referred to in paragraph 11 above;

(b) Supporting the International Bureau by testing new releases and passing on user feedback regarding their use of WIPO Sequence; and

(c) Collaborating on any further revisions of WIPO ST.26, if required, to further facilitate its implementation by Offices and applicants while remaining aligned with the requirements of INSDC and the Universal Protein Resource (UniProt).

14. Regarding revisions to WIPO ST.26, the Sequence Listings Task Force will continue deliberations on whether there should be a removal of the minimum length requirement defined in WIPO ST.26 and/or an amendment to require representation of certain amino acid and nucleotide analogs by the corresponding unmodified residue symbol. These changes will require a substantive update to the Standard, if approved.

15. The CWS is invited to:

(a) note the contents of the present document in particular the proposals by the USPTO and the EPO which require substantive changes to WIPO ST.26, as referred to in paragraphs 7 and 11;

(b) discuss the survey process and scope, and potential survey questions as referred to paragraph 12 above; and

(c) the work plan of the Sequence Listings Task Force, as detailed above in paragraphs 13 and 14.

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