

## **Patent Cooperation Treaty (PCT) Working Group**

**Twelfth Session  
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### **SEQUENCE LISTINGS — IMPLEMENTATION OF WIPO STANDARD ST.26**

*Document prepared by the International Bureau*

#### **SUMMARY**

1. The Working Group is invited to provide guidance to the International Bureau in its efforts to develop a formal proposal for changes to the PCT legal framework required to implement the move from the current PCT Sequence Listing Standard to new WIPO Standard ST.26, for consideration by the relevant PCT bodies in 2020. It is further invited to provide guidance as to the input the International Bureau should provide to the Sequence Listings Task Force of the Committee on WIPO Standards (CWS) on the potential need to further modify WIPO Standard ST.26 and developing software tools to support the preparation, filing and processing of sequence listings under that Standard.

#### **BACKGROUND**

2. The Committee on WIPO Standards (CWS), at its fourth reconvened session in March 2016, adopted WIPO Standard ST.26 “Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings using XML (eXtensible Markup Language)”. The CWS further revised ST.26 at its fifth session in May/June 2017 and at its sixth session in October 2018. The most recent version of WIPO Standard ST.26 (version 1.2) is available on the WIPO website in Part 3 of the *Handbook on Industrial Property Information and Documentation*.<sup>1</sup>

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<sup>1</sup> <https://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf>

3. At the fifth session of the CWS in May/June 2017, the CWS agreed on January 1, 2022, as the date for transition from WIPO Standard ST.25 to ST.26, to be applicable to any national or international application filed on or after that date, and requested the Sequence Listings (SEQL) Task Force (see paragraph 18 of the Summary by the Chair of the session, document CWS/5/21):

- (a) to support the International Bureau by providing users' requirements and feedback on the authoring and validation tool;
- (b) to support the International Bureau in the consequential revision of the PCT Administrative Instructions; and
- (c) to prepare necessary revisions of WIPO Standard ST. 26 upon request by the CWS.

4. Implementation of WIPO Standard ST.26 in respect of international applications filed on or after January 1, 2022, will require amendments to the PCT Regulations to be adopted by the PCT Assembly in September/October 2020, to enter into force on January 1, 2022, and major modifications to be made to the Administrative Instructions.

5. The key issues to be addressed in the context of the envisaged move from the PCT Sequence Listing Standard to WIPO Standard ST.26 include:

- (a) Unlike the current PCT Sequence Listing Standard set out in Annex C of the Administrative Instructions, WIPO Standard ST.26 does not cater for the submission of a sequence listing on paper or in an electronic format other than XML, such as PDF. Consequently, it will become strongly preferable for sequence listings to be filed as part of an international application in electronic form. Where this is not possible, international applications filed on paper will need to be accompanied by a sequence listing in electronic form submitted on physical media, thus in essence re-introducing "mixed-mode" filings into the PCT.
- (b) In order to maintain the current PCT approach with regard to language requirements for language-dependent "free text" contained in a sequence listing (the PCT requires language-dependent "free text" to be repeated in the main part of the description of the international application in the language thereof), it will be necessary to clearly define whether any such "free text" permitted to be used in a sequence listing is (entirely or effectively) "*language-independent*" or "*language-dependent*" and thus potentially requires translation for the purposes of national phase processing (for a detailed explanation of the PCT language requirements related to sequence listings, see paragraphs 12 to 28, below).
- (c) Receiving Offices will not be required to perform any checks on the contents of purported sequence listing files. Rather, the contents will be checked by the International Authorities. However, it is likely that most international applications containing sequence listings will be filed using online filing systems and the receiving Office may see the results of automatic validations at that stage. Consideration will need to be given to the tools available to applicants, receiving Offices and International Authorities for validating the various requirements of WIPO Standard ST.26, the effects of failing validation at different stages and the options available for making corrections.

6. A first round of discussions of the issues to be addressed in the context of the envisaged move to WIPO Standard ST.26 was held by the Working Group at its eleventh session in 2018, summarized in the Summary by the Chair (document PCT/WG/11/26, paragraphs 105 to 107) as follows:

"105. Discussions were based on documents PCT/WG/11/24 and 24 Cor.

“106. Delegations noted that a number of issues remained to be finalized in relation to the introduction of WIPO Standard ST.26. Offices would need time to complete their preparations. Legal implications needed to be assessed for cases where sequence listings were submitted in ST.25 format for an earlier application but needed to be submitted in ST.26 format for a later application claiming priority; the software tool would also need to assist applicants and Offices with such cases. Issues of added and deleted sequences also needed to be further explored. The software tool needed to be accessible to users in multiple languages. The practical and legal implications of expecting sequence listings for paper filings to be submitted on physical media needed to be assessed. Consideration should be given to the question whether the normal provisions concerning changing the filing date or incorporation by reference would work as intended for cases where a sequence listing was omitted from an international application at the time of filing. Issues concerning translation of language-dependent “free text” and the assistance which might be given by the IT tool remained. It was noted that a variety of drafting improvements would be required to ensure that all provisions reliably achieved their intended aims.

“107. The Working Group noted the contents of document PCT/WG/11/24 and 24 Cor. and invited the International Bureau to continue working towards an implementation of WIPO Standard ST.26 in the PCT, which would be effective and consistent with the needs of national Offices.”

## **PRELIMINARY DRAFT PROPOSALS**

7. Transition from the PCT Sequence Listing Standard set out in Annex C of the Administrative Instructions to WIPO Standard ST.26 for PCT purposes will require amendments to the PCT Regulations and modifications to the Administrative Instructions, in addition to development of procedures and support tools. The Annexes to the present document contain *preliminary* drafts of:

- (a) proposed amendments to the PCT Regulations (see Annex I);
- (b) proposed modifications to the main body of the PCT Administrative Instructions (see Annex II); and
- (c) proposed modifications to Annex C to the Administrative Instructions (see Annex III);

taking into account the discussions by the Working Group at its eleventh session and further discussions in the Sequence Listing Task Force of the CWS since then, as well as the considerations set out in the main body of the present document. Detailed explanations are given in “*Comments*” on proposed amendments and modifications of particular Rules and Sections of the Administrative Instructions set out in the Annexes.

8. Similar to the current PCT Sequence Listing Standard, the new Standard seeks to allow applicants to draw up a single sequence listing in a patent application acceptable for international, regional and national procedures. In addition, its purpose is to enhance the accuracy and quality of presentations of sequences for easier dissemination. This will facilitate the searching of sequence data and enable the exchange of sequence data in electronic form and its incorporation into computerized databases hosted by sequence database providers.

9. The preliminary draft proposals set out in the Annexes to the present document aim to establish a practical way of processing international applications containing sequence listings, taking the above aims into account. In particular, this document highlights the issues which will require further detailed consideration over the coming year by the International Bureau and the

CWS SEQL Task Force, with a view to developing a formal proposal for consideration by the Working Group in the first half of 2020 and adoption by the PCT Assembly in September/October 2020.

10. The proposed modifications to Annex C take the form of a complete re-draft of that Annex. The approach taken is to set out a consolidated explanation of the overall PCT procedures involved in filing and processing of sequence listings. To that end, it contains a number of duplications with certain provisions set out in the PCT Regulations (Annex I) and in the main body of the Administrative Instructions (Annex II), as well as with WIPO Standard ST.26. Furthermore, it contains certain provisions which, from a strictly legal point of view, might not be required but which provide background information to clarify the purpose of certain provisions. It has been drafted in a way that, in the case of duplications, aims to make clear whether any particular requirement is based on a particular Rule in the PCT Regulations, a particular Section of the main body of the Administrative Instructions, or is a new instruction being set out specifically within that Annex.

11. One issue which would appear to deserve particular attention in the context of moving from the PCT Sequence Listing Standard to WIPO Standard ST.26 is that of the language related requirements related to “free text” contained in a sequence listing, as further elaborated on in the following paragraphs.

## LANGUAGE-RELATED REQUIREMENTS

### Current Approach

12. The sequence listing part of the description of an international application is a special case when considering the filing date requirement under Article 11(1)(ii) that the international application is to be filed in a language which is accepted by the receiving Office under Rule 12.1(a), as further explained in paragraphs 13 to 17, below. In general, the receiving Office will, when checking whether the international application complies with the filing date related language requirements under Article 11(1)(ii), only check the main part of the description for compliance with Article 11(1)(ii) but not any sequence listing part of the description (see Rule 20.1(c)).

13. This, however, is not meant to say that language requirements are not important in the context of filing and processing of sequence listings. Generally speaking, during the international phase, it is important for the International Searching Authority and the International Preliminary Examining Authority (during any Chapter II procedure) to be able to understand any language-dependent free text contained in any sequence listing part of the description to carry out international search and, where applicable, international preliminary examination of the application. Similarly, during the national phase, it is equally important for designated and elected Offices before which the application has entered the national phase to be able to understand any such text matter. Moreover, the public must be able to understand any language-dependent free text contained in a sequence listing following its international publication as part of the disclosure requirements.

14. To achieve this, the current PCT Sequence Listing Standard (set out in Annex C of the Administrative Instructions) prescribes the use of “controlled vocabulary” (as set out in Appendix 2 of Annex C) for describing sequences contained in the sequence listing part of the description. This “controlled vocabulary” is, or is considered to be, “language-independent”, so that questions relating to the need for a translation for the purposes of international search or preliminary examination, or for national phase purposes, do not arise.

15. On the other hand, in addition to prescribing the use of “controlled vocabulary”, the current PCT Sequence Listing Standard also permits the use of “free text” as a value format to describe certain characteristics of a sequence. According to paragraph 33 of the Standard, “[f]ree text is

a wording describing characteristics of the sequence under numeric identifier <223> (Other information) which does not use language-independent vocabulary". According to paragraph 35, any such "free text" shall preferably be in English (but can also be submitted in any other language).

16. Current Rule 5.2(b) requires any such "free text" to be repeated in the main part of the description, in the language of the international application. This ensures that, during the international phase, the International Searching Authority and the International Preliminary Examining Authority, and, during the national phase of procedures, the designated and elected Offices will always have such "free text" available to it in a language accepted by it for international search or international preliminary examination and for national phase processing, respectively, be that as part of the international application as filed (or as corrected in accordance with Rule 13*ter*.1(f)), or as part of a translation of the international application (including any "free text" repeated in the main part of the description, in the language thereof) required for international or national phase processing. Consequently, the applicant usually will only have to prepare the sequence listing once, upon filing of the international application, and will not be required to furnish a new sequence listing to an International Authority or to any designated or elected Office only because of the need to translate any language-dependent "free text" contained in that listing into a language accepted by that Authority or Office.

17. On the other hand, where any such language-dependent "free text" is not repeated in the main part of the description in the language thereof, the International Authority concerned is required to invite the applicant to furnish a correction to include such "free text" in the main part of the description, in the language thereof (see current Rules 13*ter*.1(f) and 13*ter*.2). This is a requirement intended not so much for the benefit of the International Authority (it applies even if the language-dependent "free text" is already in a language which is accepted by it for the purposes of international search or international preliminary examination) but mainly for the benefit of the applicant. Where any language-dependent "free text" is repeated in the main part of the description, and thus in any translation thereof, the applicant will not be required to furnish a new sequence listing containing any "free text" in the language accepted for national phase processing (Rule 49.5(a-bis)).

#### Language-Related Requirements Following the Move to WIPO Standard ST.26

18. Similar to the current PCT Sequence Listing Standard, WIPO Standard ST.26 prescribes the use of "controlled vocabulary" that must be used when describing the features of a sequence, that is, annotations of regions or sites of interest as set out in Annex I to the Standard. This "allowed" controlled vocabulary comprises: nucleotide codes (Section 1 of Annex I); abbreviations for modified nucleotides (Section 2 of Annex I); amino acid codes (Section 3 of Annex I); abbreviations for modified amino acids (Section 4 of Annex I); feature keys for nucleotide sequences (Section 5 of Annex I); qualifiers for nucleotide sequences (Section 6 of Annex I); feature keys for amino acid sequences (Section 7 of Annex I); and qualifiers for amino acid sequences (Section 8 of Annex I).

19. Under the Standard, "qualifiers" are used to supply certain information about features in addition to that conveyed by the feature key and feature location. There are several types of allowed "value formats" to accommodate different types of information conveyed by qualifiers, namely specific terms, enumerated values (for example, a number or date), "free text" and sequences.

20. Of the controlled vocabulary allowed to be used when describing the features of a sequence (see paragraph 18, above), the following is, or is considered to be, *language-independent*:

- (a) the nucleotide codes set out in Section 1 of Annex I of the Standard and the amino acid codes set out in Section 3;

- (b) the abbreviations for modified nucleotides set out in Section 2 and the abbreviations for modified amino acids set out in Section 4 as the only permitted values for the certain qualifiers;
- (c) the names of feature keys set out in Sections 5 and 7, and the names of qualifiers set out in Sections 6 and 8, notwithstanding that many of the allowed names of feature keys and qualifiers are in English or are English abbreviations (see, for example, feature keys 5.1 “C-region” and 7.18 “MOD\_RES” (abbreviation of “modification of a residue”); and qualifiers 6.5 “cell\_type” and 8.3 “ORGANISM”);
- (d) all “value formats” set out in Sections 5, 6, 7 and 8 allowed to be used to accommodate different types of information conveyed by qualifiers other than “free text” (that is, specific terms, enumerated values like a number or date, and sequences), notwithstanding that many of these allowed “value formats” contain elements in English or English abbreviations or are recognizably derived from English or Latin words (see, for example, qualifier 6.15 “direction”, with the value format: “left, right or both”).
21. As at present, questions relating to the need for a translation of any such “language-independent controlled vocabulary” for the purposes of international search or preliminary examination, or for national phase purposes, do not arise.
22. On the other hand, as is the case for the current PCT Sequence Listing Standard, WIPO Standard ST.26 (in Sections 6 and 8 of Annex I) also permits the use of “free text” as a value format for certain qualifiers in sequences. According to paragraph 85 of the Standard, “[f]ree text is a type of value format for certain qualifiers (as indicated in Annex I), presented in the form of a descriptive text phrase that should preferably be in the English language”.
23. Unlike the current PCT Sequence Listing Standard, WIPO Standard ST.26 requires the entire information contained in an electronic sequence listing, except for the information given in the elements “applicant’s name”, “inventor name” and “invention title”, to be composed of printable characters from the Unicode Basic Latin code table (excluding certain reserved characters defined in WIPO Standard ST.26; accented Latin characters are also not permitted). This means that it will not be possible to submit a ST.26 compliant sequence listing with any language-dependent “free text” in languages not composed of such Basic Latin characters, such as, in particular, Chinese, Japanese or Korean.
24. While the permission of “free text” in ST.26 is very similar to the current PCT Sequence Listing Standard (except for the fact that such free text may not be in languages not composed of Basic Latin characters), WIPO Standard ST.26 permits the use of such “free text” in respect of many more qualifiers than the current Standard. The qualifiers for which the use of “free text” is permitted are set out in Sections 6 and 8 of Annex I of WIPO Standard ST.26. In essence, the “free text” permissible for these qualifiers falls into three different categories:
- (a) some “free text” is *entirely language-independent* since, while being described as “free text” and not controlled by a DTD, the expected format is specified as a “number” or “code” which does not vary between languages (example: WIPO Standard ST.26, Annex I, 6.16, qualifier “EC-number”; definition: “Enzyme Commission number for enzyme product of sequence”; value format: “free text”; example: “<INSDQualifier\_value>1.1.2.4</INSDQualifier\_value>”);
- (b) some “free text” may be *effectively language-independent* because the expected values are personal names (albeit, where relevant, transliterated into Latin characters or lacking accents) or internationally used terms for an organism (example: WIPO Standard ST.26, Annex I, 6.27, qualifier “host”; definition “natural (as opposed to laboratory) host to the organism from which sequenced molecule was obtained”; value format: “free text”; example: “<INSDQualifier\_value>Homo sapiens</INSDQualifier\_value>”);

(c) some “free text” is *always language-dependent*, taking the form of genuinely “free text” comments (example: WIPO Standard ST.26, Annex I, 6.21, qualifier “function”; definition: “function attributed to a sequence”; value format: “free text”; example: “<INSDQualifier\_value>essential for recognition of cofactor</INSDQualifier\_value>”).

25. Unfortunately, WIPO Standard ST.26 in its current form does not clearly define whether the “free text” which is permitted to be used to describe a particular qualifier is (entirely or effectively) “*language-independent*” or (always) “*language-dependent*”. Moreover, it does not limit the “free text” to be used for a particular qualifier to just one of the above mentioned categories, so that it is possible to use “a mix” of “free text” falling into all of the above mentioned three categories as an allowed value format for a particular qualifier. This makes it almost impossible for applicants to know for sure which “free text” to include in the main part of the description in the language thereof so as to comply with PCT Rule 5.2(b) and to maintain the possibility to furnish a sequence listing only once, for the purposes of both international and national phase procedures. In theory, to be on the safe side, an applicant would appear to be required to repeat all “free text” which could be considered to be language-dependent (including any “free text” falling into the second category “essentially language-independent”) in the main part of the description.

26. To overcome this difficulty, there would appear to be two options. The first option would be to modify WIPO Standard ST.26 so as to clearly identify those qualifiers whose value format “free text” was always *considered to be* “language-dependent” and which thus needed to be repeated in its entirety in the main part of the description in the language thereof. On the other hand, any “free text” used for qualifiers not so identified would always be *considered to be* “language-independent” and thus would not be required to be repeated in the main part of the description in the language thereof. However, while such a modification of WIPO Standard ST.26 would assist the continued use of the current PCT approach with regard to “free text”, as described in paragraphs 12 to 17, above, it would appear contrary to the approach agreed by the SEQ Task Force to not include any procedural provisions in WIPO Standard ST.26 (noting that the translation requirements for any free text would appear to be a procedural issue).

27. The second option would be, as far as international applications are concerned, to identify those qualifiers whose value format “free text” was always *considered to be* “language-dependent” in the PCT itself (for example, in an Appendix to Annex C of the PCT Administrative Instructions). However, while such a clarification in the PCT itself could, if so decided by the Assembly of the Patent Law Treaty (PLT), also apply to national applications filed under the national law of PLT Contracting States, States not party to the PLT would have to provide such clarification in their applicable national laws, with the risk that different requirements would be applied by different States.

28. Either way, so as to assist applicants in the preparation of a PCT Rule 5.2(b) compliant main part of the description of an international application, the software tool currently developed by the International Bureau (“WIPO Sequence”) will include a feature which would automatically extract relevant “free text” for (yet to be determined) specific qualifiers for an easy insertion by the applicant in the main part of the description (under the header “Sequence Listing Free Text”; see Section 204(viii) of the Administrative Instructions). This might be in the form of a table, with columns such as SEQ ID No., feature key, qualifier and qualifier value, and two columns showing the relevant “free text”, one in the language in which it appears in the sequence listing, and the other showing that same “free text” in the language of the main part of the description.

29. Further discussion will be required on the two options set out in paragraphs 26 and 27, above,. Further work might also envisage allowing the translations to be coded as a supplementary XML file (that is, a file not forming part of the application), identifying the relevant locations of each feature within the sequence listing and allowing tools to render sequences with annotations in either the original language or a translation.

30. In addition to the need to clearly identify those qualifiers whose value format “free text” was always *considered to be* “language-dependent”, two further changes to the current approach with regard to language requirements related to “free text” contained in a sequence listing would appear desirable, as outlined in the following paragraphs.

31. Firstly, it is noted that one of the main aims of WIPO Standard ST.26 is to allow sequence data to be exchanged in electronic form and introduced into computerized databases hosted by sequence database providers. Whereas, at present, sequences are normally uploaded into such databases without any annotations describing the features of a particular sequence, WIPO Standard ST.26 aims to also enable the upload of such annotations into such databases. However, such an upload would require any language-dependent annotations to be in English, as it would appear that English would be the only language accepted by the sequence database providers for that purpose.

32. In order to present an incentive for applicants to furnish any language-dependent “free text” in English, the Regulations could be amended so as to require:

- (a) any International Searching Authority and any International Preliminary Examining Authority, for the purposes of international search and preliminary examination; and
- (b) any designated or elected Office, for the purposes of national phase processing;

to accept English (the language preferably to be used for any language-dependent “free text”, according to WIPO Standard ST.26) for any language-dependent “free text”, even if English is not otherwise accepted by that Authority or that Office for the purposes of international search, preliminary examination or national phase processing, respectively. Moreover, the Regulations could be amended to provide that, if any language-dependent “free text” was presented in English, the applicant would not have to repeat any such “free text” in the main part of the description in the language thereof, since any such “free text” in English would be acceptable for all international phase and national phase processing purposes. This would set a strong incentive to file of sequence listings in a form that could be imported reliably into search databases.

33. Secondly, it would appear desirable to amend the Regulations so as to fill a gap in the present procedures governing the processing of sequence listing by clarifying that, where any language-dependent “free text” was not in English and not repeated in the main part of the description in the language thereof, after the applicant had been invited to submit a correction under Rule 5.2(b) (that is, to repeat the free text in the main part of the description in the language thereof), the International Authority concerned would be required to carry out the search or preliminary examination only to the extent that a meaningful search or preliminary examination could be carried out without such correction.

#### VALIDATION AND OPPORTUNITIES FOR CORRECTION

34. The software tools being developed for the preparation and validation of sequence listings should ideally mean that any formal defect in a sequence listing can be detected by the filing software and rectified before the applicant submits the sequence listing. In practice, however, it is likely that errors will occur, resulting in a need for checks and opportunities for correction by the applicant:

- (a) While applicants will be free to prepare sequence listings using any software desired, applicants will be strongly encouraged to use the tool currently being developed by the International Bureau in association with the CWS SEQL Task Force, which will provide validations against most of the requirements of the Standard, allowing applicants to correct errors before an application is filed. Decisions will be required on how strictly to



enforce some of the requirements under the Standard, such as the limitations on characters permitted in “free text” qualifiers, taking into account that one of the aims of WIPO Standard ST.26 is acceptance of sequence data by the database providers.

(b) The receiving Office will not be required to check the content of sequence listings, but in most cases will have received them through online filing, which may have run validations and reported defects of format of a nature which can be detected by the filing software. In this case, the receiving Office should ideally warn the applicant and offer an opportunity to correct such a formal defect immediately. The question of such “advisory” notices of defects is not specific to sequence listings (most commonly, such “advisory notice” is desired where a receiving Office sees that drawings have not converted well, but not so badly that the application should be considered withdrawn if no correction is made) and is not considered further in this document.

(c) The International Searching Authority (and, where relevant, the International Preliminary Examining Authority) should validate the format of the sequence listing and consider its content. If a sequence listing is missing in an application where a listing is required, or if a listing is not compliant, the Authority may invite the applicant to submit a correction. If there is an obvious error in the content, the Authority may invite the applicant to submit a rectification.

(d) The applicant may, where appropriate, submit an Article 34 amendment to the International Preliminary Examining Authority, for example, removing some sequences no longer relevant to the claims, or else adding sequences disclosed in the main part of the description that should have been included in the sequence listing as filed, provided that any such removal or addition does not result in a disclosure beyond the disclosure of the application as originally filed.

(e) Amendments and corrections may be required in the national phase.

35. The software tools being developed will help to create and validate corrected and amended sequence listings, and may assist Offices in comparing different versions of listings. However, preparation and comparison of different listing versions will remain difficult for both applicants and Offices. Consequently, the proposals in the Annexes seek to encourage approaches which minimize the number of occasions when a new listing will be required after filing.

## **ENVISAGED ENTRY INTO FORCE AND TRANSITIONAL ARRANGEMENTS**

36. As stated in paragraph 3, above, the CWS agreed on a “big bang” scenario with January 1, 2022, as the date for transition from WIPO Standard ST.25 to ST.26, to be applicable to any national or international application filed on or after that date. The new Standard would therefore apply to national and international applications filed on or after that date (see also document CWS/5/7 Rev. 1 and Rev. 1 Add.).

37. At this stage, and subject to the successful completion of the ongoing development of the necessary software tools, it is envisaged that the International Bureau will present a formal proposal for the amendment of the PCT Regulations and the modifications of the Administrative Instructions to the PCT Working Group for consideration at its 2020 session and adoption by the PCT Assembly at its September/October 2020 session, together with proposed entry into force provisions along the following lines:

(a) the amendments to the Regulations and the modifications to the Administrative Instructions would enter into force on January 1, 2022;

(b) the Regulations and Administrative Instructions as in force as of January 1, 2022, would apply to any international application filed on or after January 1, 2022;

(c) the Regulations and Administrative Instructions as in force on December 31, 2021, would continue to apply to any international application filed before January 1, 2022 (even if a later date, after January 1, 2022, is accorded as the international filing date).

38. There would appear to be no need for any other transitional arrangements for PCT purposes, though it may be desirable to modify WIPO Standard ST.25 to make clear that it refers to the version of Annex C of the PCT Administrative Instructions in force on December 31, 2021.

39. *The Working Group is invited:*

*(a) to comment on the issues set out in paragraphs 7 to 38 of this document, having regard to the preliminary draft proposed amendments to the PCT Regulations set out in Annex I to this document and the preliminary draft proposed modifications to the PCT Administrative Instructions set out in Annexes II and III to this document; and*

*(b) to offer guidance to the International Bureau on matters which it should consider or might invite the CWS to explore further.*

[Annexes follow]

PRELIMINARY DRAFT  
PROPOSED AMENDMENTS TO THE PCT REGULATIONS<sup>2</sup>

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<sup>2</sup> Proposed additions and deletions are indicated, respectively, by underlining and striking through the text concerned.

## Rule 5

### The Description

#### 5.1 [No Change]

#### 5.2 Nucleotide and/or Amino Acid Sequence Disclosure

(a) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences which, pursuant to the Administrative Instructions, are required to be included in a sequence listing, the description shall include a separate part of the description (“sequence listing part of the description”) ~~contain~~ containing a sequence listing complying with those ~~the standard provided for in the Administrative~~ Instructions and presented ~~as a separate part of the description in accordance with that standard~~ in the form of a single electronic file in XML format in accordance with those Instructions (“compliant sequence listing”).

*[COMMENT: The substance of the new requirements for the filing and processing of sequence listings under the PCT is mostly defined by reference to WIPO Standard ST.26 (as distinct from the present arrangement, where the standard is contained entirely within Annex C of the Administrative Instructions). It is nevertheless proposed to refer to the Administrative Instructions rather than to ST.26 directly in order to allow fine details of version control and specific procedures and implementation for the PCT to be specified more clearly. The term “compliant sequence listing” is proposed for use in later provisions, noting that only very limited checks, if any, would be applied to sequence listings by some receiving Offices, but compliance may be tested and required by International Authorities or designated and elected Offices.]*

(a-bis) Any electronic file purporting or appearing to be a sequence listing received on or before the date on which the receiving Office determines that the papers purporting to be an international application fulfill all of the requirements under Article 11(1) shall be considered to form part of the description, whether or not that listing is referred to in the main part of the description or in the request.

*[Rule 5.2(a-bis), continued]*

*[COMMENT: The proposed addition of new paragraph (a-bis) is not directly related to the transition from the PCT Sequence Listing Standard to WIPO Standard ST.26 as such, but seeks to minimize the risk of listings failing to be considered to form part of the international application as filed due to their being mislabeled, a risk which may increase if filings are made with the application body on paper and an electronic sequence listing on a physical medium. Appropriate guidance would have to be included in the Receiving Office Guidelines to set out how receiving Offices should process such electronic files, which will be considered to form part of the description, taking into account the format (paper or electronic) in which the remainder of the application was filed.]*

(b) Where the sequence listing part of the description contains any language-dependent free text as defined in the ~~standard provided for in the~~ Administrative Instructions, that language-dependent free text shall, if not in English, also appear in the main part of the description in the language thereof.

*[COMMENT: See paragraphs 26 and 27 of the main body of the present document. Either WIPO Standard ST.26 or the PCT Administrative Instructions should be modified to clearly identify those qualifiers in respect of which “language-dependent free text” is permitted to be used for a qualifier and thus, in accordance with Rule 5.2(b) as proposed to be amended, always to be repeated in the main part of the description in the language thereof, unless it is in English. For a detailed explanation of the language related requirements for sequence listings, see paragraphs 12 to 33 of the main body of the present document, above.]*

## Rule 12

### Language of the International Application and Translations for the Purposes of International Search and International Publication

#### 12.1 *Languages Accepted for the Filing of International Applications*

(a) [No change] An international application shall be filed in any language which the receiving Office accepts for that purpose.

(b) [No change] Each receiving Office shall, for the filing of international applications, accept at least one language which is both:

(i) a language accepted by the International Searching Authority, or, if applicable, by at least one of the International Searching Authorities, competent for the international searching of international applications filed with that receiving Office, and

(ii) a language of publication.

(c) [No change] Notwithstanding paragraph (a), the request shall be filed in any language of publication which the receiving Office accepts for the purposes of this paragraph.

(d) Notwithstanding paragraph (a), ~~any text matter contained in~~ the sequence listing part of the description referred to in Rule 5.2(a) shall be presented in accordance with ~~the standard provided for in~~ the Administrative Instructions.

*[COMMENT: It is proposed to exempt the entire sequence listing part of the description from the language requirements under Rule 12, similar to current Rule 20.1(c) and Rules 12.3(b), 12.4(b) and 49.5. For a detailed explanation of the language related requirements for sequence listings, see paragraphs 12 to 33 of the main body of the present document, above.]*

12.1 bis to 12.2 [No Change]

12.3 *[No Change] Translation for the Purposes of International Search*

(a) [No change] Where the language in which the international application is filed is not accepted by the International Searching Authority that is to carry out the international search, the applicant shall, within one month from the date of receipt of the international application by the receiving Office, furnish to that Office a translation of the international application into a language which is all of the following:

(i) a language accepted by that Authority, and

(ii) a language of publication, and

(iii) a language accepted by the receiving Office under Rule 12.1(a), unless the international application is filed in a language of publication.

(b) [No change] Paragraph (a) shall not apply to the request nor to any sequence listing part of the description.

*[COMMENT: There does not appear to be any need to change Rule 12.3(a) and (b).]*

(c) to (e) [No change]

12.4 *[No Change] Translation for the Purposes of International Publication*

(a) Where the language in which the international application is filed is not a language of publication and no translation is required under Rule 12.3(a), the applicant shall, within 14 months from the priority date, furnish to the receiving Office a translation of the international application into any language of publication which the receiving Office accepts for the purposes of this paragraph.

*[Rule 12.4, continued]*

(b) Paragraph (a) shall not apply to the request nor to any sequence listing part of the description.

*[COMMENT: There does not appear to be any need to change Rule 12.4(a) or (b).]*

(c) to (e) [No change]



## Rule 13ter

### Nucleotide and/or Amino Acid Sequence Listings

#### 13ter.1 Procedure before the International Searching Authority

(a) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences which, pursuant to the Administrative Instructions, are required to be included in a sequence listing but the international application as filed does not contain a compliant sequence listing referred to in Rule 5.2(a), the International Searching Authority may invite the applicant to furnish to it, for the purposes of the international search, such a compliant sequence listing ~~in electronic form complying with the standard provided for in the Administrative Instructions~~, unless such listing ~~in electronic form~~ is already available to it in a form and manner acceptable to it, and to pay to it, where applicable, the late furnishing fee referred to in paragraph (c), within a time limit fixed in the invitation.

*[COMMENT: It is proposed to amend Rule 13ter.1(a) so as to take into account that WIPO Standard ST.26 more closely defines which sequences are or are not required to be included in a sequence listing and because a listing is, by definition, required to be submitted in electronic form.]*

~~(b) Where at least part of the international application is filed on paper and the International Searching Authority finds that the description does not comply with Rule 5.2(a), it may invite the applicant to furnish, for the purposes of the international search, a sequence listing in paper form complying with the standard provided for in the Administrative Instructions, unless such listing in paper form is already available to it in a form and manner acceptable to it, whether or not the furnishing of a sequence listing in electronic form is invited under paragraph (a), and to pay, where applicable, the late furnishing fee referred to in paragraph (c), within a time limit fixed in the invitation.~~

*[COMMENT: It is proposed to delete paragraph (b), noting that it is no longer possible to file a compliant sequence listing in paper form.]*

*[Rule 13ter.1, continued]*

(c) The furnishing of a sequence listing in response to an invitation under paragraph (a) ~~or (b)~~ may be subjected by the International Searching Authority to the payment to it, for its own benefit, of a late furnishing fee whose amount shall be determined by the International Searching Authority but shall not exceed 25% of the international filing fee referred to in item 1 of the Schedule of Fees, not taking into account any fee for each sheet of the international application in excess of 30 sheets, ~~provided that a late furnishing fee may be required under either paragraph (a) or (b) but not both.~~

*[COMMENT: The proposed amendments of paragraph (c) are consequential on the proposed deletion of paragraph (b) (see above).]*

(d) If the applicant does not, within the time limit fixed in the invitation under paragraph (a) ~~or (b)~~, furnish the required compliant sequence listing referred to in Rule 5.2(a) and pay any required late furnishing fee, the International Searching Authority shall only be required to search the international application to the extent that a meaningful search can be carried out without the compliant sequence listing.

*[COMMENT: The proposed amendments to paragraph (d) are consequential on the proposed deletion of paragraph (b) (see above) and on the proposed use of the term "compliant sequence listing referred to in Rule 5.2(a) throughout the Regulations.]*

(e) Any sequence listing not contained in the international application as filed, whether furnished in response to an invitation under paragraph (a) ~~or (b)~~ or otherwise, shall not form part of the international application; ~~but~~ however, pursuant to Article 34(2)(b), this paragraph shall not prevent the applicant from amending the description in relation to the disclosure of any nucleotide and/or amino acid sequences contained in the international application as filed, whether or not those sequences were included in a compliant sequence listing referred to in Rule 5.2(a) ~~pursuant to Article 34(2)(b).~~

[Rule 13ter.1(e), continued]

[COMMENT: It is proposed to amend paragraph (e) so as to clarify that it is possible to amend the description in relation to any sequences disclosed in the description, whether or not those sequences were presented in the form of a compliant sequence listing (of course only where such an amendment would not result in any added subject matter).]

(f) Where the International Searching Authority finds that the description does not comply with Rule 5.2(b) because any language-dependent free text contained in the sequence listing part of the description is not in English and does not also appear in the main part of the description in the language thereof, it shall invite the applicant to submit, within a time limit fixed in the invitation:

(i) the required correction in the language of the international application as filed or, where a translation of the application is required under Rule 12.3(a) or 12.4(a), in the language of that translation;

(ii) verified by the applicant or the person having translated the language-dependent free text in a statement to the effect that, to the best of the applicant's or the person's knowledge, the translation is a complete and faithful translation of the language-dependent free text contained in the sequence listing part of the description.

Rule 26.4 shall apply *mutatis mutandis* to any correction offered by the applicant. The International Searching Authority shall transmit a copy of any ~~the~~ correction submitted by the applicant to the receiving Office and to the International Bureau.

[Rule 13ter.1(f), continued]

[COMMENT: It is proposed to amend paragraph (f) so as to clarify the language in which the applicant is invited to furnish any correction under Rule 5.2(b) (that is, the language of any language-dependent “free text” included in the sequence listing which, pursuant to Rule 5.2(b), if not in English, is to be repeated in the main part of the description in the language thereof). If the language in which the correction is to be submitted is not English, the International Searching Authority may also invite the applicant to furnish the required correction also in English, so as to enable that Authority to submit the sequence listing and any language-dependent free text in English to the sequence database providers. For a detailed explanation of the language related requirements for sequence listings, see paragraphs 12 to 33 of the main body of the present document, above.]

(g) Where a translation of the international application is required under Rule 12.3(a) but the applicant does not, within the time limit fixed in the invitation under paragraph (f), furnish the required correction in the language of that translation, the International Searching Authority shall only be required to search the international application to the extent that a meaningful search can be carried out without that translation, unless the language-dependent text matter referred to in Rule 5.2(b) is in English.

[COMMENT: It is proposed to add a new paragraph (g) so as to clarify that, where a translation of the application is required for the purposes of the international search but the applicant does not also furnish a translation of any language-dependent “free text” included in the sequence listing into the language of that translation, the International Searching Authority would only be required to carry out the search “to the extent that a meaningful search can be carried out without such translation, unless the language-dependent “free text” was in English (which all Authorities would be required to accept as a language in which language-dependent “free text” can be included in a sequence listing). For a detailed explanation of the language related requirements for sequence listings, see paragraphs 12 to 33 of the main body of the present document, above.]

13ter.2 [No Change] Procedure before the International Preliminary Examining Authority

Rule 13ter.1 shall apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.

[COMMENT: No change would appear to be required to Rule 13ter.2; the procedure set out in Rule 13ter.1 would apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.]

13ter.3 *Sequence Listing for Designated Office*

No designated Office shall require the applicant to furnish to it a sequence listing other than a compliant sequence listing referred to in Rule 5.2(a) ~~complying with the standard provided for in the Administrative Instructions.~~

*[COMMENT: The proposed amendments to Rule 13ter.3 are consequential on the proposed use of the term “compliant sequence listing referred to in Rule 5.2(a) throughout the Regulations. See Rule 49.5(a-bis), below, with regard to the language related requirements during the procedure before a designated Office.]*

## Rule 20

### International Filing Date

20.1 *[No change] Determination under Article 11(1)*

(a) [No change] Promptly after receipt of the papers purporting to be an international application, the receiving Office shall determine whether the papers fulfill the requirements of Article 11(1).

(b) [No change]

(c) [No change] For the purposes of Article 11(1)(ii), it shall be sufficient that the part which appears to be a description (other than any sequence listing part thereof) and the part which appears to be a claim or claims be in a language accepted by the receiving Office under Rule 12.1(a).

(d) [No change]

20.2 to 20.5 *[No change]*

20.6 *Confirmation of Incorporation by Reference of Elements and Parts*

(a) The applicant may submit to the receiving Office, within the applicable time limit under Rule 20.7, a written notice confirming that an element or part is incorporated by reference in the international application under Rule 4.18, accompanied by:

*[Rule 20.6(a), continued]*

(i) a sheet or sheets embodying the entire element as contained in the earlier application or embodying the part concerned; where the element concerned is the element referred to in Article 11(1)(iii)(d) and contains a sequence listing in electronic form, or where the part concerned is such sequence listing in electronic form or a part thereof, the written notice shall be accompanied by a copy or copies of the sequence listing in electronic form as contained in the earlier application submitted in accordance with the Administrative Instructions;

*[COMMENT: The proposed amendments to paragraph (a)(i) are consequential on the fact that it will no longer be possible to submit a sequence listing on “sheets” of paper but only in electronic form. Where the element to be incorporated by reference is the description and that description contains a sequence listing in electronic form, or where the part of the description which is to be incorporated by reference is the sequence listing or a part thereof, then the entire sequence listing as contained in the earlier application may have to be submitted in three copies if sent on a physical medium. Further thought will have to be given to the case in which the applicant wishes to incorporate by reference a sequence listing on paper or pdf which was contained in an earlier application filed before January 1, 2022.]*

(ii) to (iv) [No change]

(b) and (c) [No change]

20.7 and 20.8 [No Change]

## Rule 49

### Copy, Translation and Fee under Article 22

49.1 to 49.4 [No Change]

49.5 [No Change] *Contents of and Physical Requirements for the Translation*

(a) [No change] For the purposes of Article 22, the translation of the international application shall contain the description (subject to paragraph (a-bis)), the claims, any text matter of the drawings and the abstract. If required by the designated Office, the translation shall also, subject to paragraphs (b), (c-bis) and (e):

(i) contain the request,

(ii) if the claims have been amended under Article 19, contain both the claims as filed and the claims as amended (the claims as amended shall be furnished in the form of a translation of the complete set of claims furnished under Rule 46.5(a) in replacement of all the claims originally filed), and

(iii) be accompanied by a copy of the drawings.

(a-bis) No designated Office shall require the applicant to furnish to it:

(i) a translation of ~~any text matter contained in~~ the sequence listing part of the description if such sequence listing part complies with Rule 12.1(d); and

(ii) a translation of any language-dependent free text as defined in the Administrative Instructions if that free text is in English or, if not in English, if the description complies with Rule 5.2(b).



*[Rule 49.5(a-bis), continued]*

*[COMMENT: It is proposed to amend paragraph (a-bis) so as to require designated Offices to accept English as a language for any language-dependent text matter contained in a sequence listing. For a detailed explanation of the language related requirements for sequence listings, see paragraphs 12 to 33 of the main body of the present document, above.]*

(b) to (l) [No change]

49.6 [No Change]

**Rule 76**

**Translation of Priority Document;**

**Application of Certain Rules to Procedures before Elected Offices**

76.1, 76.2 and 76.3 *[Remain Deleted]*

76.4 *[No Change]*

76.5 *[No Change] Application of Certain Rules to Procedures before Elected Offices*

Rules 13~~ter~~.3, 20.8(c), 22.1(g), 47.1, 49, 49~~ter~~*bis*, 49~~ter~~ and 51~~ter~~*bis* shall apply, provided that:

(i) any reference in the said Rules to the designated Office or to the designated State shall be construed as a reference to the elected Office or to the elected State, respectively;

(ii) any reference in the said Rules to Article 22, Article 23(2) or Article 24(2) shall be construed as a reference to Article 39(1), Article 40(2) or Article 39(3), respectively;

(iii) to (v) *[No change]*

*[COMMENT: No change would appear to be required to Rule 76.5.]*

*[Annex II follows]*

PRELIMINARY DRAFT  
PROPOSED MODIFICATIONS TO THE PCT ADMINISTRATIVE INSTRUCTIONS

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## Section 101

### **[No change] Abbreviated Expressions and Interpretation**

(a) [No change] In these Administrative Instructions:

(i) to (xi) [No change]

(xii) [No change] the expressions “sequence listing”, “sequence listing forming part of the international application” and “sequence listing not forming part of the international application” have the same meaning as in Annex C.

*[COMMENT: No change would appear to be needed to Section 101 of the Administrative Instructions.]*

(b) [No change]

## Section 204

### Headings of the Parts of the Description

(a) The headings of the parts of the description shall preferably be as follows:

(i) to (vi) [No change]

(vii) ~~[Deleted] for matter referred to in Rule 5.2(a), "Sequence Listing";~~

*[COMMENT: It is proposed to delete item (vii) of paragraph (a), noting that it will only be possible to submit sequence listings as separate electronic files. Consequently, there will be no purpose for a section with a heading "Sequence Listing". Any description of or reference to the sequence listing could be placed elsewhere in the main part of the description.]*

(viii) [No change] for matter referred to in Rule 5.2(b), "Sequence Listing Free Text".

*[COMMENT: For a detailed explanation of the language related requirements for sequence listings, see paragraphs 12 to 33 of the main body of the present document, above.]*

(b) [No change]

## Section 207

### Arrangement of Elements and Numbering of Sheets of the International Application

(a) In effecting the sequential numbering of the sheets of the international application in accordance with Rule 11.7, the elements of the international application shall be placed in the following order:

(i) [No change] the request;

(ii) the description (if applicable, including the sequence listing free text referred to in Rule 5.2(b) but excluding the sequence listing part of the description referred to in [Rule 5\(2\)\(a\)](#) ~~item (vi) of this paragraph~~);

(iii) [No change] the claims;

(iv) [No change] the abstract;

(v) if applicable, the drawings;

(vi) ~~[Deleted] if applicable, the sequence listing part of the description.~~

*[COMMENT: It is proposed to delete item (vi) of paragraph (a), noting that it will only be possible to submit sequence listings as separate electronic files but not on "sheets" on paper which are to be placed in a particular order within the international application.]*

(b) The sequential numbering of the sheets shall be effected by using the following separate series of numbering:

(i) [No change] the first series applying to the request only and commencing with the first sheet of the request;

*[Section 207(b), continued]*

(ii) [No change] the second series commencing with the first sheet of the description (as referred to in paragraph (a)(ii)) and continuing through the claims until the last sheet of the abstract;

(iii) if applicable, a further series applying to the sheets of the drawings only and commencing with the first sheet of the drawings; the number of each sheet of the drawings shall consist of two Arabic numerals separated by a slant, the first being the sheet number and the second being the total number of sheets of drawings (for example, 1/3, 2/3, 3/3);

~~(iv) if applicable, a further series applying to the sequence listing part of the description, commencing with the first sheet of that part.~~

*[COMMENT: It is proposed to delete item (iv) of paragraph (b), noting that it will only be possible to submit sequence listings as separate electronic files but not on "sheets" on paper which are to be numbered with a particular series of numbering.]*

## Section 208

### Sequence Listings

Any sequence listing, ~~whether on paper or in electronic form,~~ whether forming part of the international application or not forming part of the international application, shall comply with Annex C.

*[COMMENT: The proposed amendment of Section 208 is consequential on the fact that it will no longer be possible to submit a compliant sequence listing on paper.]*



## Section 309

### Procedure in the Case of Later Submitted Sheets or Sequence Listing in Electronic Form Furnished for the Purposes of Incorporation by Reference

(a) This Section applies, subject to paragraph (f), to any later submitted sheets and any later submitted sequence listing in electronic form which accompany a notice confirming under Rule 20.6 that an element or part embodied in those sheets or in that sequence listing was incorporated by reference.

(b) Where any later submitted sheets as referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, within the applicable time limit referred to in Rule 20.7 and the receiving Office makes a finding under Rule 20.6(b), the receiving Office shall:

(i) [No change] indelibly mark, in the middle of the bottom margin of each later submitted sheet, the words “INCORPORATED BY REFERENCE (RULE 20.6)”, or their equivalent in the language of publication of the international application;

*[COMMENT: The marking of incorporated sequence listings will need to be reviewed in the more general context of improvements to the processing of application bodies and other documents processed in XML format. This should be done by the application of metadata – the sequence listing file itself should not be changed, but its file type and references to it should make clear the status of whether the listing has been incorporated or not. Further thought will have to be given to the case in which the applicant wishes to incorporate by reference a sequence listing on paper or pdf which was contained in an earlier application filed before January 1, 2022.]*

(ii) notify the applicant that the element or part contained in the later submitted sheets, or contained in the later submitted sequence listing in electronic form, is considered to have been contained in the international application or purported international application on the date when sheets were first received and that that date has been accorded or retained, as the case may be, as the international filing date;

*[Section 309(b), continued]*

(iii) keep in its files a copy of the later submitted sheets marked under item (i), a copy of the later submitted sequence listing in electronic form and a copy of the notice under Rule 20.6(a);

(iv) where transmittals under Article 12(1) have already been made, notify the International Bureau and the International Searching Authority accordingly, and transmit ~~the~~any later submitted sheets marked under item (i) to the said Bureau and a copy thereof to the said Authority; in the case of any later submitted sequence listing in electronic form, the receiving Office shall transmit one copy thereof to the International Bureau and one to the said Authority;

(v) where transmittals under Article 12(1) have not yet been made, attach ~~the~~any later submitted sheets marked under item (i) and the notice under Rule 20.6(a) to the record copy and a copy thereof to the search copy; in the case of any later submitted sequence listing in electronic form, the receiving Office shall attach one copy thereof to the record copy and one copy thereof to the search copy.

(c) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, within the applicable time limit referred to in Rule 20.7 and the receiving Office makes a finding under Rule 20.6(c), the receiving Office shall, subject to Section 310*bis*:

(i) effect the required correction of the international filing date or accord as the international filing date the date of receipt of ~~any~~the later submitted sheets or the date of receipt of any later submitted sequence listing in electronic form or, where both later submitted sheets and a later submitted sequence listing are received on different dates, the date of receipt which is later;

*[Section 309(c), continued]*

(ii) notify the applicant that the content of any~~the~~ later submitted sheets and/or of any later submitted sequence listing in electronic form, is not considered to have been contained in the international application or purported international application on the date when sheets were first received and that the international filing date has been accorded as, or corrected to, as the case may be, the date on which the new sheets were, or the sequence listing in electronic form was, received, as the case may be;

(iii) keep in its files a copy of any~~the~~ later submitted sheets, of any sequence listing in electronic form and of the notice under Rule 20.6(a);

(iv) where transmittals under Article 12(1) have already been made, notify the International Bureau and the International Searching Authority accordingly and transmit a copy of the corrected first and last sheets of the request, any~~the~~ later submitted sheets, any later submitted sequence listing in electronic form and the notice under Rule 20.6(a) to the said Bureau and a copy thereof to the said Authority;

(v) where transmittals under Article 12(1) have not yet been made, attach any~~the~~ later submitted sheets, any later submitted sequence listing in electronic form and the notice under Rule 20.6(a) to the record copy and a copy thereof to the search copy.

(d) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, within the applicable time limit referred to in Rule 20.7 but the purported international application still does not fulfill the requirements of Article 11(1), the receiving Office shall proceed as provided in Rule 20.4, but not before the expiration of the time limit under Rule 20.7.

[Section 309, continued]

(e) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, after the expiration of the applicable time limit referred to in Rule 20.7, the receiving Office shall proceed as provided in Section 310*ter*.

(f) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, but a missing element or part contained in those sheets or in that sequence listing cannot be incorporated by reference in the international application under Rules 4.18 and 20.6 because of the operation of Rule 20.8(a), the receiving Office shall:

(i) inform the applicant that the notice under Rule 20.6(a) confirming the incorporation by reference of the missing element or part has been disregarded;

(ii) proceed in accordance with Section 310(b), which shall apply *mutatis mutandis*, as if the notice under Rule 20.6(a) were a correction furnished under Rule 20.3(b)(i), or a missing part furnished under Rules 20.5(b) or (c), as the case may be; and

(iii) proceed in accordance with Section 310*bis*(b) where the applicant requests, within the time limit under Rule 20.5(e), that the missing part concerned be disregarded.

### Section 313

#### Documents Filed with the International Application; Manner of Marking the Necessary Annotations in the Check List

(a) and (b) [No change]

(c) Any sequence listing in electronic form not forming part of the international application, ~~whether on paper or in electronic form,~~ that is furnished for the purposes of the international search to the receiving Office ~~together with the international application or~~ subsequent to the filing of the international application, shall be transmitted to the International Searching Authority together with the search copy. Where such a sequence listing in electronic form is received by the receiving Office after the transmittal of the search copy, that sequence listing shall be promptly transmitted to the International Searching Authority.

*[COMMENT: Proposed amendments to Section 313(c) are consequential on the fact that it is no longer possible to submit sequence listings in paper form and on the proposed addition of new Rule 5.2(a-bis), according to which any electronic file purporting or appearing to be a sequence listing received on or before the date on which the receiving Office determines that the papers purporting to be an international application fulfill all of the requirements under Article 11(1) is to be considered to form part of the description.]*

## Section 513

### Sequence Listings

(a) [No change] Where the International Searching Authority receives a correction of a defect under Rule 13~~ter~~.1(f), it shall:

(i) indelibly mark, in the upper right-hand corner of each replacement sheet, the international application number and the date on which that sheet was received;

(ii) indelibly mark, in the middle of the bottom margin of each replacement sheet, the words "SUBSTITUTE SHEET (Rule 13~~ter~~.1(f))" or their equivalent in the language of publication of the international application;

(iii) indelibly mark on the letter containing the correction, or accompanying any replacement sheet, the date on which that letter was received;

(iv) keep in its files a copy of the letter containing the correction or, when the correction is contained in a replacement sheet, the replaced sheet, a copy of the letter accompanying the replacement sheet, and a copy of the replacement sheet;

(v) promptly transmit any letter and any replacement sheet to the International Bureau, and a copy thereof to the receiving Office.

*[COMMENT: The procedures concerning the sequence listing "free text" in the main part of the description would remain unchanged.]*

*[Section 513, continued]*

(b) Where the international search report and the written opinion of the International Searching Authority are based on a compliant sequence listing not forming part of the international application but furnished for the purposes of the international search, the international search report and the written opinion of the International Searching Authority shall so indicate.

(c) Where a meaningful international search cannot be carried out and a meaningful written opinion, as to whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable, cannot be established because a compliant sequence listing is not available to the International Searching Authority ~~in the required form~~, that Authority shall so state in the international search report or declaration referred to in Article 17(2)(a), and in the written opinion.

(d) ~~The International Searching Authority shall indelibly mark, on the first sheet of any sequence listing on paper which does not form part of the international application but was furnished for the purposes of the international search, the words "SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION" or their equivalent in the language of publication of the international application.~~ Where ~~such a~~ sequence listing for the purposes of the international search is furnished ~~in electronic form~~ on a physical medium, that Authority shall physically label that medium in accordance with the procedures in Annex C ~~accordingly~~.

*[COMMENT: It is not necessary to regulate the metadata used internally by International Searching Authorities to identify the different types of sequence listing which have been transmitted electronically, rather than submitted on physical media; the means of identifying the files for the purpose of exchange with the International Bureau or other Offices are set out in Annex F and/or the "minspec" document exchange specification.]*

*[Section 513, continued]*

(e) The International Searching Authority shall:

(i) keep in its files one copy of any sequence listing in electronic form, ~~whether on paper or in electronic form~~, which does not form part of the international application but was furnished for the purposes of the international search; and

(ii) ~~where the sequence listing which does not form part of the international application but was furnished for the purposes of the international search is in electronic form~~, transmit one copy thereof to the International Bureau together with the copy of the international search report. If that listing in electronic form is filed on a physical medium in less than the number of copies required by the International Searching Authority, that Authority shall be responsible for the preparation of the additional copy and shall have the right to fix a fee for performing that task and to collect such fee from the applicant.

(f) ~~Any~~ Each International Searching Authority ~~which requires, for the purposes of the international search, the furnishing of a sequence listing in electronic form~~ shall notify the International Bureau ~~accordingly. In that notification, the Authority shall specify~~ of the means of transmittal of the sequence listing in electronic form accepted by it in accordance with Annex F. The International Bureau shall promptly publish details of the notification in the Gazette.

*[COMMENT: It would be mandatory for all International Searching Authorities to accept sequence listings in electronic form, though this could be limited to physical media.]*



## Section 610

### Sequence Listings

(a) Where the written opinion of the International Preliminary Examining Authority or the international preliminary examination report is based on a [compliant](#) sequence listing not forming part of the international application but furnished for the purposes of the international preliminary examination, the written opinion and the international preliminary examination report of the International Preliminary Examining Authority shall so indicate.

(b) Where a meaningful written opinion of the International Preliminary Examining Authority cannot be established, or a meaningful international preliminary examination cannot be carried out, as to whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable, because a [compliant](#) sequence listing is not available to the International Preliminary Examining Authority ~~in the required form~~, that Authority shall so state in the written opinion and in the international preliminary examination report.

(c) ~~The International Preliminary Examining Authority shall indelibly mark, on the first sheet of any sequence listing on paper which does not form part of the international application but was furnished for the purposes of the international preliminary examination, the words "SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION" or their equivalent in the language of publication of the international application.~~ Where ~~such a~~ [sequence listing for the purposes of the international preliminary examination](#) is furnished in electronic form on a physical medium, that Authority shall physically label that medium [in accordance with the procedures in Annex C](#) ~~accordingly~~.

[COMMENT: As for Section 513(d).]

*[Section 610, continued]*

(d) The International Preliminary Examining Authority shall keep in its files one copy of any sequence listing, ~~whether on paper or~~ in electronic form, which does not form part of the international application but was furnished for the purposes of the international preliminary examination.

(e) ~~Any Each- International Preliminary Examining Authority which requires, for the purposes of the international preliminary examination, the furnishing of a sequence listing in electronic form~~ shall notify the International Bureau ~~accordingly. In that notification, the Authority shall specify~~ of the means of transmittal of the sequence listing in electronic form accepted by it in accordance with Annex F. The International Bureau shall promptly publish details of the notification in the Gazette.

*[COMMENT: As for Section 513(f).]*

(f) Where the national Office or intergovernmental organization that acted as the International Searching Authority also acts as the International Preliminary Examining Authority, any compliant sequence listing not forming part of the international application but furnished to that Office or organization for the purposes of the international search shall be considered to have been furnished to it also for the purposes of the international preliminary examination.

### Section 703

#### Filing Requirements; Basic Common Standard

(a) [No change] An international application may, subject to this Part, be filed in electronic form if the receiving Office has notified the International Bureau in accordance with Rule 89bis.1(d) that it is prepared to receive international applications in such form.

(a-bis) Notwithstanding paragraph (a), any receiving Office shall be required to accept a sequence listing in electronic form on a physical medium:

(i) where the remainder of the international application is filed on paper; or

(ii) where the international application is filed in electronic form but it is either not possible or not practical to include the sequence listing within the package containing the remainder of the international application;

and shall, in respect of each International Searching Authority which is competent for the searching of international applications filed with it, specify at least one form of physical medium in accordance with Annex F which it accepts for the filing of such sequence listings which is also accepted by such Authority.

*[COMMENT: Given the difficulties of obtaining notifications from all receiving Offices, most of which would never actually receive such a physical medium, it may be appropriate to indicate a default, where in the absence of a notification the receiving Office must accept a sequence listing on a physical medium of a type accepted by the relevant International Searching Authority. Consideration might alternatively be given to an amendment to Rule 19.4, allowing receiving Offices which do not wish to deal with physical media to forward the international application to the International Bureau to act as receiving Office.]*

(b) to (f) [No change]

## Section 707

### Calculation of International Filing Fee and Fee Reduction

(a) [No change] Where an international application is filed in electronic form, the international filing fee shall, subject to paragraph (a-bis), be calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the physical requirements prescribed in Rule 11.<sup>3</sup>

(a-bis) Where ~~a sequence listing is contained in an~~ the international application as filed contains an electronic file purporting or appearing to be a sequence listing ~~in electronic form~~, the calculation of the international filing fee shall, in the calculation of the number of sheets, not take into account any ~~sheet of the sequence listing if that listing is presented as a separate part of the description in accordance with Rule 5. 2(a) and is in the electronic document format specified in paragraph 40 of Annex C~~ material contained in such an electronic file.

*[COMMENT: The receiving Office would not be required to perform any checks on the format of the sequence listings – notably, receiving Offices which have no electronic filing systems and simply accept the listing on a physical medium may assume that any appropriately labeled disk is a compliant listing. This is intended simply to allow page fees to be collected in cases where a file is provided which is clearly not intended to be a sequence listing, for example if a PDF file of further description or drawings had been attached, mislabeled as sequence listings.]*

(b) [No change]

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<sup>3</sup> *Editor's Note:* Noting that Rule 11 leaves some flexibility as to the margins of the sheets (see Rule 11.6) and the size of the characters (see Rule 11.9(d)), the international filing fee should be calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the minimum margin and character size requirements. In practice, however, the receiving Office should not print out the international application but rather rely on the number of pages of the international application as calculated by the electronic filing software and indicated in the request.

## Section 710

### Notification and Publication of Receiving Offices'

#### Requirements and Practices

(a) A notification by a receiving Office to the International Bureau under Rule 89*bis*.1(d) and Section 703(a) that it is prepared to receive international applications in electronic form shall indicate, where applicable:

(i) the electronic document formats (including, where applicable, the versions of such electronic document formats), means of transmittal, types of electronic packages, electronic filing software and types of electronic signature specified by it under Section 703(*a-bis*), (b)(i) to (iv) and (c), and any options specified by it under the basic common standard;

(ii) to (vii) [no change]

(b) to (d) [No change]

[Annex III follows]

## ANNEX C

### INSTRUCTIONS RELATING TO THE PRESENTATION OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS IN INTERNATIONAL PATENT APPLICATIONS UNDER THE PCT

#### INTRODUCTION

1. The Instructions set out in this Annex apply to international applications filed on or after January 1, 2020.
2. Pursuant to Rule 5.2(a), “[w]here the international application contains disclosure of one or more nucleotide and/or amino acid sequences which, pursuant to the Administrative Instructions, are required to be included in a sequence listing, the description shall include a separate part of the description (“sequence listing part of the description”) containing a sequence listing complying with those Instructions and presented in the form of a single electronic file in accordance with those Instructions (“compliant sequence listing”).” Pursuant to Section 208, “[a]ny sequence listing, whether forming part of the international application or not forming part of the international application, shall comply with Annex C” (this Annex).
3. This Annex provides the Instructions referred to above in relation to the filing and processing of sequence listings, whether forming part of an international applications or not forming part of an international application.

#### DEFINITIONS

4. For the purposes of these Instructions:
  - (a) the expression “sequence listing” has the same meaning as defined in WIPO Standard ST.26;
  - (b) “nucleotide” and “amino acid” have the same meanings as in WIPO Standard ST.26;
  - (c) the expression “sequence listing forming part of the international application” means a sequence listing contained in the international application as filed, including any sequence listing or part thereof which is included in the international application under Rule 20.5(b) or (c), which is considered to have been contained in the international application under Rule 20.6(b), or which has been corrected under Rule 26, rectified under Rule 91 or amended under Article 34(2); or a sequence listing included in the international application by way of an amendment under Article 34(2)(b) of the description in relation to sequences contained in the international application as filed;

(d) the expression “sequence listing not forming part of the international application” means a sequence listing which does not form part of the international application but is furnished for the purposes of the international search or international preliminary examination.

#### **RELATIONSHIP WITH WIPO STANDARD ST.26**

5. WIPO Standard ST.26 shall apply to any nucleotide and amino acid sequence disclosure in an international application, notably with regard to:

- (a) the question as to whether such disclosure is to be included in a sequence listing;
- (b) the manner in which disclosures are to be presented;
- (c) the question as to when the use of “free text” is permitted as a value format for certain qualifiers in sequences and the identification of those qualifiers for which language-dependent “free text” may be used (see Sections 6 and 8 in Annex I to WIPO Standard ST. 26); and

*[COMMENT: Paragraph (c) is drafted on the assumption that WIPO Standard ST.26 is further modified to specify those qualifiers for which language-dependent text may be used. See paragraphs 26 and 27 in the main body of the present document.]*

- (d) the Document Type Definition (DTD) for a sequence listing in XML (eXtensible Markup Language);

subject to the specific requirements set out in this Annex.

6. Following any revision of WIPO Standard ST.26, the Director General shall decide a date from which the revised version of that Standard shall apply to international applications and publish that information in the Gazette. Sequence listings shall be presented in accordance with the version of WIPO Standard ST.26 so applicable to an international application on the date on which it is filed.

#### **SEQUENCES WHICH MUST BE PRESENTED IN A LISTING**

7. In accordance with WIPO Standard ST.26, a sequence for which inclusion in a sequence listing is required for the purposes of Rule 5.2 is one that is disclosed anywhere in an international application by enumeration of its residues and can be represented as:

- (a) an unbranched sequence or a linear region of a branched sequence containing ten or more specifically defined nucleotides, wherein adjacent nucleotides are joined by:

- (i) a 3' to 5' (or 5' to 3') phosphodiester linkage; or
  - (ii) any chemical bond that results in an arrangement of adjacent nucleobases that mimics the arrangement of nucleobases in naturally occurring nucleic acids; or
- (b) an unbranched sequence or a linear region of a branched sequence containing four or more specifically defined amino acids, wherein the amino acids form a single peptide backbone, that is, adjacent amino acids are joined by peptide bonds.

8. In accordance with WIPO Standard ST.26, a sequence listing must not include, as a sequence assigned its own sequence identification number, any sequences having fewer than ten specifically defined nucleotides, or fewer than four specifically defined amino acids.

9. A sequence listing compliant with WIPO Standard ST.26 takes the form of an electronic file in XML format. In accordance with Rule 5.2(a), the sequence listing part of the description shall be presented separate from the main part of the description. PCT provisions do not require that the sequences themselves be presented in the main part of the description in addition to the sequence listing; however, there may be valid reasons for doing so. Where the sequences are presented within the main part of description, they may be set out in the manner considered most appropriate to present the information for the relevant purpose, rather than strictly adhering to the presentation requirements of WIPO Standard ST.26. . In the description, claims or drawings of the application, the sequences represented in the sequence listing shall be referred to by the sequence identifier and preceded by "SEQ ID NO:", even if the sequence is also embedded in the description, claims, or drawings.

## **SEQUENCE LISTINGS FORMING PART OF THE INTERNATIONAL APPLICATION**

### **ELECTRONIC FILE PURPORTING OR APPEARING TO BE A SEQUENCE LISTING**

10. In accordance with Rule 5.2(a-bis), any electronic file purporting or appearing to be a sequence listing received on or before the date on which the receiving Office determines that the papers purporting to be an international application fulfill all of the requirements under Article 11(1) shall be considered to form part of the description, whether or not that listing is referred to in the main part of the description or in the request. This is independent of the question whether or not the electronic file purporting or appearing to be a sequence listing is in fact compliant with WIPO Standard ST.26 (which is not required to be checked by the receiving Office but only by the International Searching Authority, see paragraphs 29 to 31, below).



## INTERNATIONAL APPLICATION, INCLUDING SEQUENCE LISTING, FILED IN ELECTRONIC FORM

11. Where the international application containing a sequence listing is filed in electronic form, whether transmitted by electronic or physical means, the sequence listing shall preferably form part of a package filed in accordance with Annex F, with the sequence listing indexed in accordance with the standards set out in that Annex.

12. Notwithstanding paragraph 11, any receiving Office may accept an electronic file purporting or appearing to contain a sequence listing submitted separately from the main package on the date of filing and shall accept such a separate electronic file in any case where it is not practical for the applicant to include the sequence listing as part of the main package, for example, because the file size is too large to be handled by the software used for preparing or receiving the remainder of the international application.

## SEQUENCE LISTING IN ELECTRONIC FORM WITH REMAINDER OF INTERNATIONAL APPLICATIONS FILED ON PAPER

13. In accordance with Section 703(d), any receiving Office shall be required to accept a sequence listing in electronic form filed on a physical medium of a type accepted by that Office where the remainder of the international application is filed on paper.

## SEQUENCE LISTINGS FILED ON PHYSICAL MEDIA

14. Any physical medium containing a sequence listing, whether the remainder of the international application is filed on paper or in electronic form, shall be clearly labeled "Sequence Listing" or its equivalent in the language of publication, to which the receiving Office shall add the international application number. Preferably, the physical medium used for the transmittal of the sequence listing shall be of a type accepted by both the receiving Office and the International Searching Authority chosen to carry out the international search.

15. Where a sequence listing is too large to be included on a single physical medium, it shall be split such that the files can be rejoined to form one single contiguous file without any missing or repeating contents in accordance with the procedures set out in paragraphs 2(c) and (c-bis) of Appendix IV to Annex F of these Administrative Instructions. In addition to the physical labeling appropriate to the type of physical medium, the physical media shall each be numbered, for example "DISK 1/3", "DISK 2/3", "DISK 3/3".

*[COMMENT: Some concern has been expressed over the standards used for splitting and rejoining files. This should be considered as a more general issue in the context of Appendix IV of Annex F, rather than having a provision exclusively for sequence listings.]*

16. Each receiving Office and International Authority shall notify the International Bureau of at least one of the physical media types referred to in Appendix IV of Annex F which it accepts for the purpose of the receipt of sequence listings. The International Bureau shall promptly publish any such notification in the Gazette. In the absence of such a notification, the Office or Authority shall accept physical media of any type which has been the subject of a notification in accordance with Section 710(a) or (b), or else any of the media referred to in Appendix IV of Annex F.

#### LANGUAGE RELATED REQUIREMENTS

17. WIPO Standard ST.26 prescribes the use of “controlled vocabulary” that must be used when describing the features of a sequence, that is, annotations of regions or sites of interest as set out in Annex I to the Standard. This “allowed” controlled vocabulary comprises: nucleotide codes (Section 1 of Annex I); abbreviations for modified nucleotides (Section 2 of Annex I); amino acid codes (Section 3 of Annex I); abbreviations for modified amino acids (Section 4 of Annex I); feature keys for nucleotide sequences (Section 5 of Annex I); qualifiers for nucleotide sequences (Section 6 of Annex I); feature keys for amino acid sequences (Section 7 of Annex I); and qualifiers for amino acid sequences (Section 8 of Annex I).

18. Under the Standard, “qualifiers” are used to supply certain information about features in addition to that conveyed by the feature key and feature location. There are several types of allowed “value formats” to accommodate different types of information conveyed by qualifiers, namely specific terms, enumerated values (for example, a number or date), “free text” and sequences.

19. Of the controlled vocabulary allowed to be used when describing the features of a sequence (see paragraph 18, above), the following is, or is considered to be, *language-independent*:

- (a) the nucleotide codes set out in Section 1 of Annex I of the Standard and the amino acid codes set out in Section 3;
- (b) the abbreviations for modified nucleotides set out in Section 2 and the abbreviations for modified amino acids set out in Section 4 as the only permitted values for the certain qualifiers;

(c) the names of feature keys set out in Sections 5 and 7, and the names of qualifiers set out in Sections 6 and 8, notwithstanding that many of the allowed names of feature keys and qualifiers are in English or are English abbreviations (see, for example, feature keys 5.1 “C-region” and 7.18 “MOD\_RES” (abbreviation of “modification of a residue”); and qualifiers 6.5 “cell\_type” and 8.3 “ORGANISM”);

(d) all “value formats” set out in Sections 5, 6, 7 and 8 allowed to be used to accommodate different types of information conveyed by qualifiers other than “free text” (that is, specific terms, enumerated values like a number or date, and sequences), notwithstanding that many of these allowed “value formats” contain elements in English or English abbreviations or are recognizably derived from English or Latin words (see, for example, qualifier 6.15 “direction”, with the value format: “left, right or both”).

20. Questions relating to the need for a translation of any such “language-independent controlled vocabulary” for the purposes of international search or preliminary examination, or for national phase purposes, do not arise.

21. On the other hand, WIPO Standard ST.26 (in Sections 6 and 8 of Annex I) also permits the use of “free text” as a value format for certain qualifiers in sequences. According to paragraph 85 of the Standard, “[f]ree text is a type of value format for certain qualifiers (as indicated in Annex I), presented in the form of a descriptive text phrase that should preferably be in the English language”.

22. WIPO Standard ST.26 requires the entire information contained in an electronic sequence listing, except for the information given in the elements “applicant’s name”, “inventor name” and “invention title”, to be composed of printable characters from the Unicode Basic Latin code table (excluding certain reserved characters defined in WIPO Standard ST.26; accented Latin characters are also not permitted). Consequently, it is not possible to submit a WIPO Standard ST.26 compliant sequence listing with any language-dependent “free text” in languages not composed of such Basic Latin characters.

23. The qualifiers for which the use of “free text” is permitted are set out in Sections 6 and 8 of Annex I of WIPO Standard ST.26. In essence, the “free text” permissible for these qualifiers falls into three different categories:

(a) some “free text” is *entirely language-independent* since, while being described as “free text” and not controlled by a DTD, the expected format is specified as a “number” or “code” which does not vary between languages (example: WIPO Standard ST.26, Annex I, 6.16, qualifier “EC-number”; definition: “Enzyme Commission number for enzyme product of sequence”; value format: “free text”; example: “<INSDQualifier\_value>1.1.2.4</INSDQualifier\_value>”);

(b) some “free text” may be *effectively language-independent* because the expected values are personal names (albeit, where relevant, transliterated into Latin characters or lacking accents) or internationally used terms for an organism (example: WIPO Standard ST.26, Annex I, 6.27, qualifier “host”; definition “natural (as opposed to laboratory) host to the organism from which sequenced molecule was obtained”; value format: “free text”; example: ““<INSDQualifier\_value>Homo sapiens</INSDQualifier\_value>”);

(c) some “free text” is *always language-dependent*, taking the form of genuinely “free text” comments (example: WIPO Standard ST.26, Annex I, 6.21, qualifier “function”; definition: “function attributed to a sequence”; value format: “free text”; example: “<INSDQualifier\_value>essential for recognition of cofactor</INSDQualifier\_value>”).

24. WIPO Standard ST.26 (in Sections 6 and 8 of Annex I) clearly identifies those qualifiers for which “free text” which is considered to be “*language dependent*” may be used.

*[COMMENT: Paragraphs 23 and 24 are drafted on the assumption that WIPO Standard ST.26 is further modified to specify those qualifiers for which language-dependent text may be used. See paragraphs 26 and 27 in the main body of the present document.*

25. So as to ensure that, during the international phase, the International Authorities, and, during the national phase of procedures, the designated and elected Offices can understand any such *language-dependent “free text”* if that “free text” is not in English (which must be accepted by any International Authority for the purposes of the international phase, and by any designated or elected Office for the purposes of the national phase) and not in a language which is accepted by those Authorities or those Offices, PCT Rule 5.2(b) requires any such “language-dependent free text as defined in the Administrative Instructions” (that is, any “free text” identified, in Sections 6 and 8 of Annex I of ST.26, as “language-dependent”), to be repeated in the main part of the description in the language thereof.

26. Such inclusion of any *language-dependent “free text”* in the main part of the description in the language thereof ensures that the International Authority concerned and any designated or elected Office will always have such non-English “free text” available to it in a language accepted by it for international search or international preliminary examination and for national

phase processing, respectively, be that as part of the international application as filed (or as corrected in accordance with Rule 13~~ter~~.1(f)), or as part of a translation of the international application (including any “free text” repeated in the main part of the description, in the language thereof) into a language accepted by the International Authority furnished by the applicant under Rule 12.3(a) or Rule 55.2, into a language of publication furnished by the applicant under Rule 12.4(a), or into a language accepted by the designated or elected Office furnished by the applicant under Articles 22 or 39.

27. On the other hand, any “free text” not identified in Sections 6 and 8 of Annex I to WIPO Standard ST.26 as “*language dependent*” will always be considered to be “language-independent” and does thus not have to be repeated in the main part of the description in the language thereof.

28. Where any *language-dependent* “free text” is not in English and not repeated in the main part of the description in the language thereof, the International Authority concerned is required to invite the applicant to furnish a correction to include such “free text” in the main part of the description, in the language thereof (see current Rules 13~~ter~~.1(f) and 13~~ter~~.2). This is a requirement not so much for the benefit of the International Authority (it applies even if the language-dependent “free text” is already in a language which is accepted by it for the purposes of international search or international preliminary examination) but mainly for the benefit of the applicant; it is only in case any language-dependent “free text” is indeed repeated in the main part of the description, and thus in any translation thereof, that it is guaranteed that the applicant will not be required to furnish a new sequence listing for national phase processing purposes. If such a correction has not been submitted, the applicant would be required to provide a new sequence listing, including any “free text” set out in the language accepted by the designated or elected Office for the purposes of national phase processing.

#### CHECKING BY THE RECEIVING OFFICE

##### Checking for Compliance with WIPO Standard ST.26

29. The receiving Office shall not be required to validate whether a sequence listing is compliant with WIPO Standard ST.26. However, where the Office becomes aware of a defect, for example, because its online filing processes or other Office procedures check the sequence listing file using the validation tool provided for the purpose by the International Bureau, the Office shall notify the applicant accordingly.

### Calculation of International Filing Fee

30. In accordance with Section 707(a-bis), where the international application as filed contains an electronic file purporting or appearing to be a sequence listing, the calculation of the international filing fee shall, in the calculation of the number of sheets, not take into account any material contained in such an electronic file. However, where the receiving Office determines that the electronic file in fact contains material which is clearly not a sequence listing, such as PDF pages of the main part of the description or drawings mislabeled as a sequence listing, such pages should be taken into account in the calculation of the number of sheets.

### Language Related Requirements

31. See paragraphs 17 to 28, above. As noted in paragraph 17, above, the receiving Office will, when checking whether the international application complies with the filing date related language requirements under Article 11(1)(ii), only check the main part of the description for compliance with Article 11(1)(ii) but not any sequence listing part of the description (see Rule 20.1(c)).

### **CORRECTION, RECTIFICATION AND AMENDMENT OF SEQUENCE LISTINGS**

32. Any correction under Rule 26, rectification under Rule 91 or amendment under Article 34(2)(b) of the description submitted in relation to a sequence listing forming part of the international application as filed and any sequence listing included in the international application by way of an amendment under Article 34(2)(b) of the description in relation to sequences contained in the international application as filed shall be made submitting a complete sequence listing compliant with WIPO Standard ST.26 including the relevant correction, rectification or amendment. The nature of the correction, rectification or amendment shall be clearly explained in an accompanying letter.

33. In compliance with WIPO Standard ST.26, any sequence listing referred to in paragraph 32 shall, where possible, maintain the original numbering of the sequences in the application as filed, representing any “intentionally skipped sequence” as prescribed by WIPO Standard ST.26, where necessary. Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

34. Where the sequence listing referred to in paragraph 32 as proposed to be corrected, rectified or amended is presented on physical media, the media shall be labeled “Sequence Listing – Correction”, “Sequence Listing – Rectification” or “Sequence Listing – Amendment”, as the case may be, or the equivalents in the language of publication, together with the international application number.

### **SEQUENCE LISTINGS NOT FORMING PART OF THE INTERNATIONAL APPLICATION**

35. Any sequence listing furnished under Rule 13*ter*.1, 13*ter*.2 and 45*bis*.5(c) to an International Authority for the purposes of international search or preliminary examination shall not, pursuant to Rule 13*ter*.1(e) (where applicable, by virtue of Rules 13*ter*.2 and 45*bis*.5(c)), form part of the international application. In compliance with WIPO Standard ST.26, such a sequence listing shall, where possible, maintain the original numbering of the sequences in the application as filed, representing any “intentionally skipped sequence” as prescribed by WIPO Standard ST.26, where necessary. Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

36. Paragraphs 5, 7 to 9 and 15 of this Annex shall apply *mutatis mutandis* to any sequence listing furnished under Rule 13*ter*.1, 13*ter*.2 and 45*bis*.5(c) to an International Authority for the purposes of international search or preliminary examination. Such sequence listing shall contain all sequences disclosed in the international application as filed, which meet the criteria referred to in paragraph 5, above, shall not go beyond the disclosure of the international application as filed and shall be accompanied by a statement to that effect.

37. Where such a listing is furnished on physical media, the media shall be labeled “Sequence Listing Not Forming Part of the International Application”, or its equivalent in the language of publication, together with the international application number.

### **PROCEDURE BEFORE DESIGNATED AND ELECTED OFFICES**

38. For the purposes of the procedure before a designated or elected Office before which the processing of an international application which contains the disclosure of one or more nucleotide and/or amino acid sequences has started (see Rule 13*ter*.3):

- (a) any reference to the receiving Office or the International Searching Authority or the International Preliminary Examining Authority shall be construed as a reference to the designated or elected Office concerned;
- (b) any reference to a sequence listing which is included in the international application by way of a rectification under Rule 91 or an amendment under Article 34(2)(b) of the description in relation to sequences contained in the application as filed shall be construed to also include any sequence listing included in the application, under the national law applied by the designated or elected Office concerned, by way of a rectification (of an obvious mistake) or amendment of the description in relation to sequences contained in the application as filed;

(c) any reference to a sequence listing furnished for the purposes of international search or international preliminary examination shall be construed to also include any such listing furnished to the designated or elected Office concerned for the purposes of national search or examination by that Office;

(d) the designated or elected Office concerned may invite the applicant to furnish to it, within a time limit which shall be reasonable under the circumstances, for the purposes of national search and/or examination, a sequence listing in electronic form complying with this Standard, unless such listing in electronic form is already available to that Office in a form and manner acceptable to it.

[End of Annex III and of document]